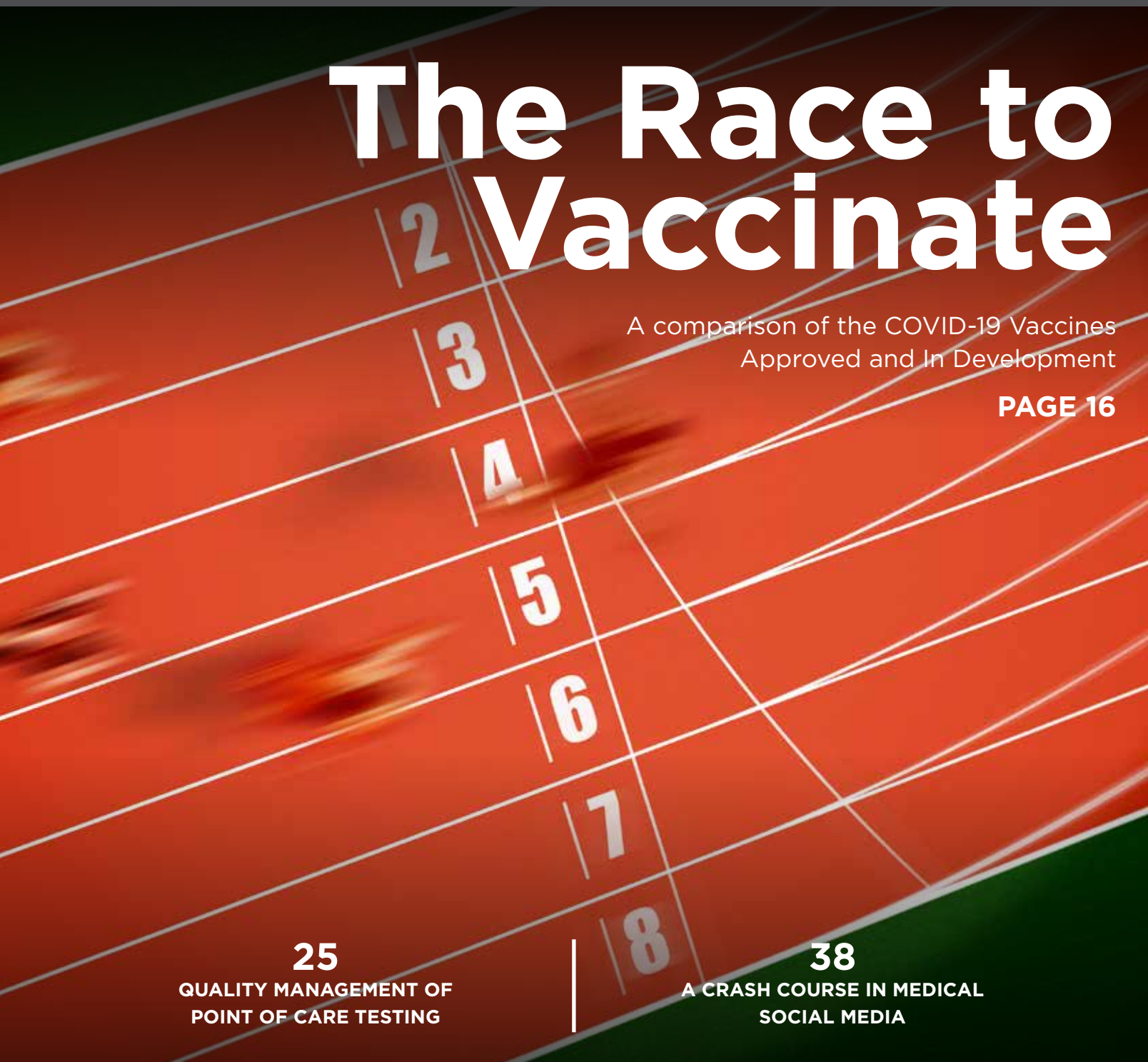
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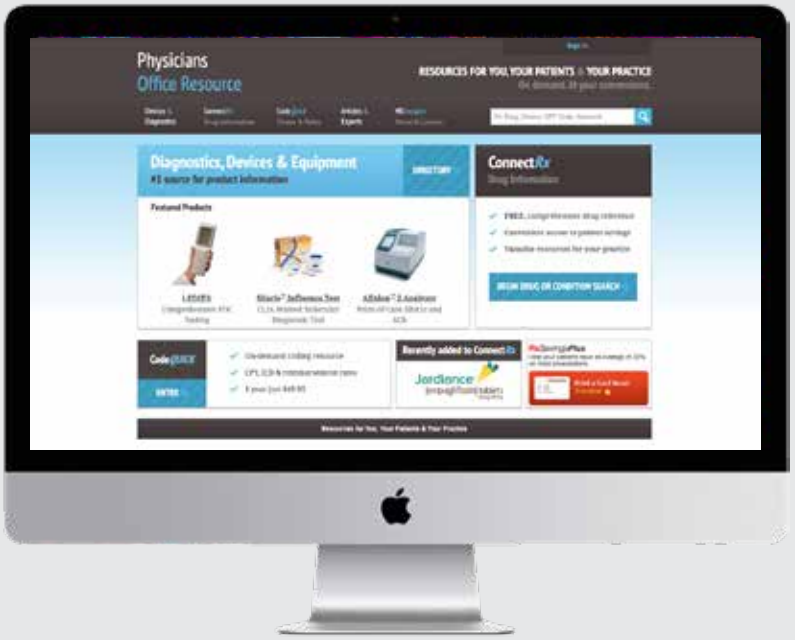
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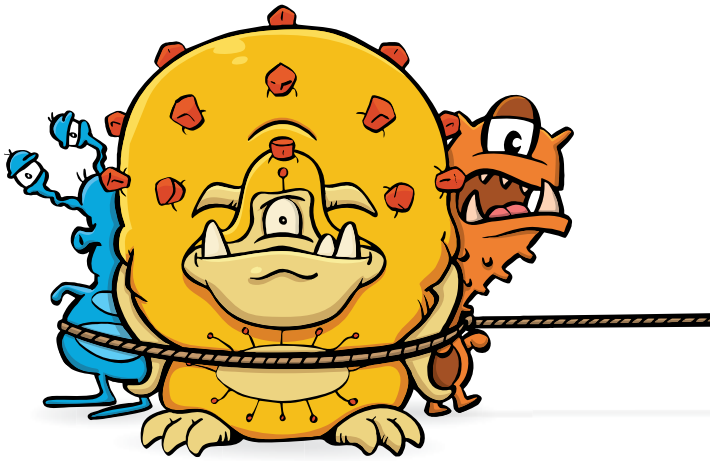
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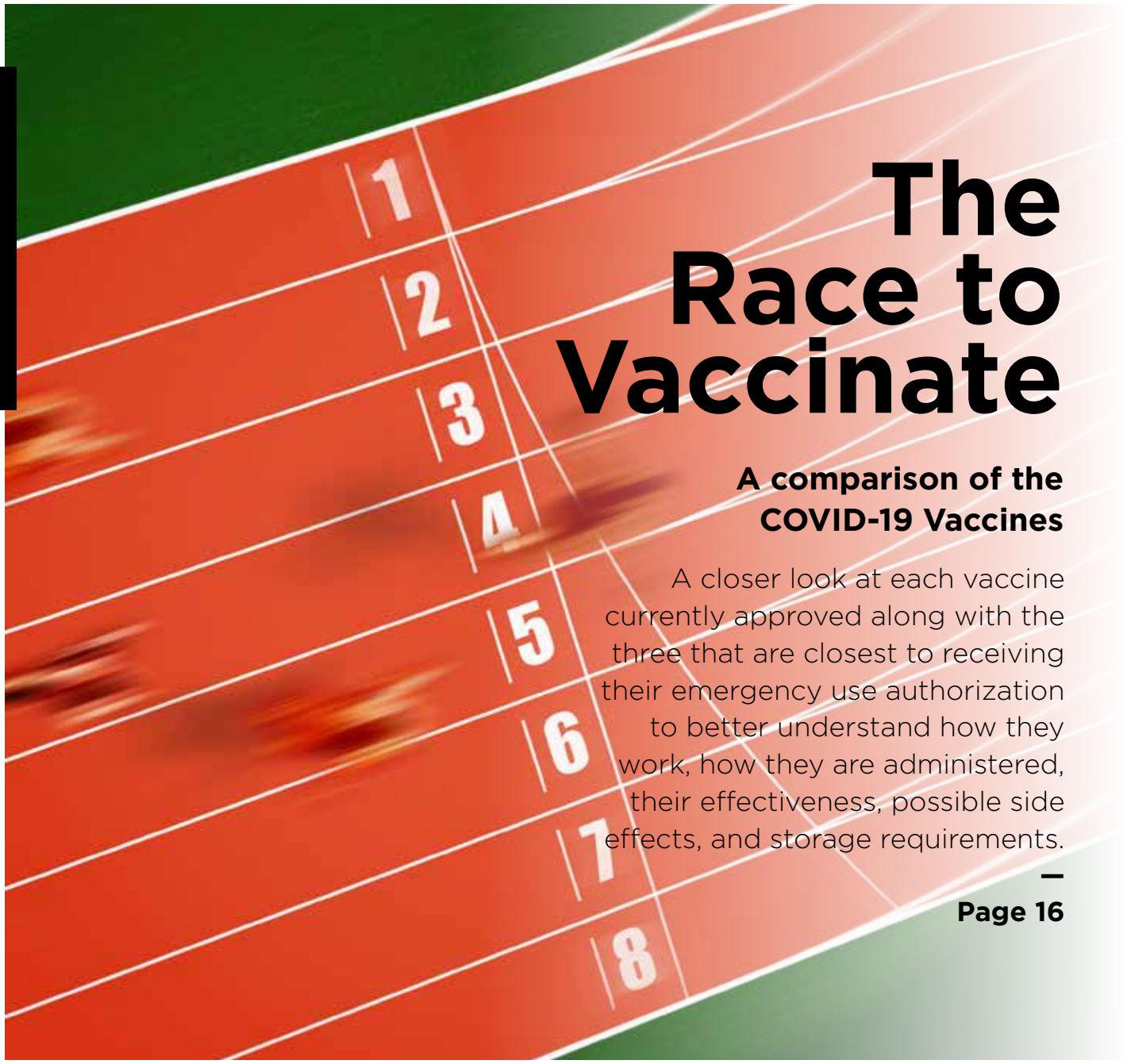
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Syndromic Testing: The Right Test, The First Time.

1. This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2 from multiple respiratory viral and bacterial organisms. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
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BFR0001-0517-01



The Race to Vaccinate

A comparison of the COVID-19 Vaccines

A closer look at each vaccine currently approved along with the three that are closest to receiving their emergency use authorization to better understand how they work, how they are administered, their effectiveness, possible side effects, and storage requirements.

—

Page 16

25

QUALITY MANAGEMENT OF POINT OF CARE TESTING

—

POCT's popularity has risen in recent years due to its convenience, timeliness, and potential to improve patient outcomes. In fact, POCT is estimated to be increasing at 10-12% annually, compared to a 6-7% annual increase for other clinical laboratory testing. Used appropriately, POCT can be a key component in meeting the goals of simultaneously improving patient outcomes and reducing healthcare costs.

38

A CRASH COURSE IN MEDICAL SOCIAL MEDIA

—

I recently discovered one of the internet's greatest contribution's to pop-culture obsessives: the Reddit AMA. In Medical parlance, "AMA" stands for "American Medical Association" but on the internet, it's short for "ask me anything." Call me uncultured, late to the game, or uninformed (actually, don't), but the internet's premiere discussion board took a few more years than normal to get its hooks in me.

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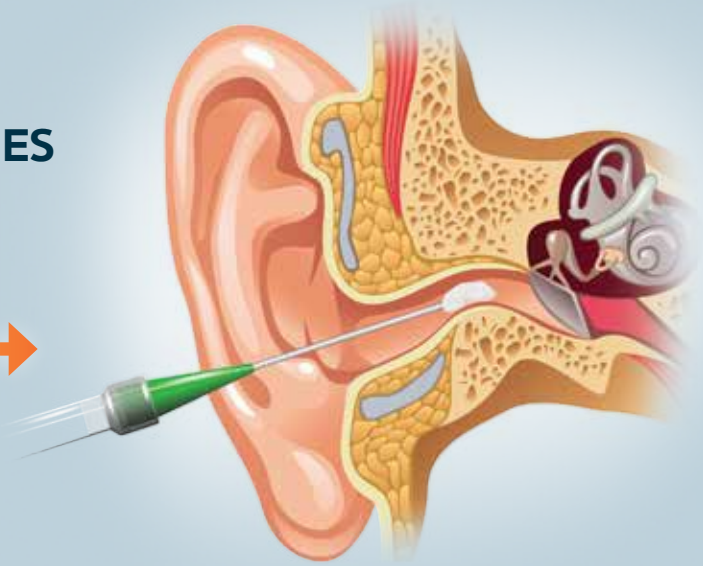
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After administration to the external ear canal, OTIPRIO warms and transitions to a gel.



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INDICATIONS AND USAGE

OTIPRIO® (ciprofloxacin otic suspension) 6% is a fluoroquinolone antibacterial indicated for the treatment of acute otitis externa in patients 6 months of age and older due to *Pseudomonas aeruginosa* and *Staphylococcus aureus*.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

OTIPRIO (ciprofloxacin otic suspension) 6% is contraindicated in patients with a history of hypersensitivity to ciprofloxacin, to other quinolones, or to any of the components of OTIPRIO.

WARNINGS AND PRECAUTIONS

Potential for Microbial Overgrowth: OTIPRIO may result in overgrowth of non-susceptible bacteria and fungi. If such infections occur, institute alternative therapy.

ADVERSE REACTIONS

Acute otitis externa clinical trial: Adverse reactions (incidence at least 2%) with OTIPRIO vs sham were: ear pruritus (2% vs 2%), headache (2% vs 1%), otitis media (2% vs 1%), and ear discomfort (2% vs 0%).

USE IN SPECIFIC POPULATIONS

Pediatric Use: The safety and effectiveness of OTIPRIO in infants below 6 months of age have not been established for the treatment of acute otitis externa.

Please see Brief Summary of Prescribing Information for OTIPRIO on the following page

ALK

OTONOMY®

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OTIPRIO® (ciprofloxacin otic suspension) 6%

Rx only

BRIEF SUMMARY OF PRESCRIBING INFORMATION FOR OTIPRIO

INDICATIONS AND USAGE

OTIPRIO is a fluoroquinolone antibacterial indicated for the treatment of acute otitis externa in patients 6 months of age and older due to *Pseudomonas aeruginosa* and *Staphylococcus aureus*.

DOSAGE AND ADMINISTRATION

Dosage and Important Administration Instructions

- OTIPRIO is for otic administration by a healthcare professional only.
- OTIPRIO is intended for single-patient use, discard unused portion.
- For acute otitis externa, administer OTIPRIO as a single 0.2 mL (12 mg) administration to the external ear canal of each affected ear of patients aged 6 months and older.

Preparation of OTIPRIO

Directions for OTIPRIO dose preparation and handling for acute otitis externa is illustrated in Figure 1 of the full prescribing information.

DOSAGE FORMS AND STRENGTHS

Otic Suspension: Each 1 mL of OTIPRIO contains a white, preservative-free, sterile otic suspension consisting of 6% (60 mg/mL) ciprofloxacin in a single-patient use glass vial.

CONTRAINDICATIONS

OTIPRIO is contraindicated in patients with a history of hypersensitivity to ciprofloxacin, to other quinolones, or to any of the components of OTIPRIO.

WARNINGS AND PRECAUTIONS

Potential for Microbial Overgrowth

OTIPRIO may result in overgrowth of nonsusceptible bacteria and fungi. If such infections occur, institute alternative therapy.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

In a single randomized, sham controlled Phase 3 clinical trial, 259 pediatric and adult patients with acute otitis externa were treated with OTIPRIO or sham administered by a healthcare professional to the external ear canal as a single dose (0.2 mL to each affected ear). The median age of the patients enrolled in the clinical trial was 34 years; 26% were pediatric patients (age 3 to 17 years), 65% were adults (age 18 to 64 years), and 8% were elderly patients (age 65 years and older).

Adverse reactions that occurred in at least 2% of OTIPRIO patients and at an incidence greater than sham are presented in Table 1.

Table 1: Adverse Reactions in Phase 3 Acute Otitis Externa Trial

Adverse Reactions	OTIPRIO (N=127)	Sham (N=132)
Ear Pruritus	2%	2%
Headache	2%	1%
Otitis Media	2%	1%
Ear Discomfort	2%	0%

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Animal reproduction studies have not been conducted with OTIPRIO. No adequate and well-controlled studies have been performed in pregnant women. Because of the negligible systemic exposure associated with clinical administration of OTIPRIO, this product is expected to be of minimal risk for maternal and fetal toxicity when administered to pregnant women.

Lactation

Risk Summary

Ciprofloxacin is excreted in human milk with systemic administration. However, because of the negligible systemic exposure after otic application, nursing infants of mothers receiving OTIPRIO should not be affected.

Pediatric Use

The safety and effectiveness of OTIPRIO for the treatment of acute otitis externa was established in 67 pediatric patients (3 through 17 years of age) who participated in the Phase 3 trial; 57% of patients were 3 through 11 years of age and 43% of patients were 12 through 17 years of age. The safety and efficacy observed in the pediatric patients was no different from the older population. OTIPRIO is indicated for the treatment of acute otitis externa in pediatric patients 6 months of age and older.

The safety and effectiveness of OTIPRIO in infants below 6 months of age have not been established for the treatment of pediatric patients with acute otitis externa.

For more detailed information, please read the full Prescribing Information.

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U.S. Patent Nos: 8,318,817, 9,205,048, 9,220,796, 9,233,068, 9,486,405, and 9,603,796

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ASSESSING AND MONITORING COVID-19 PATIENTS.

Urgent care facilities, primary care practices, and other outpatient settings at the front lines of the COVID-19 pandemic need on-site testing solutions to support patient assessment and monitoring. With-patient testing can lead to better healthcare performance by facilitating decisions that can optimize patient outcomes in real time, improving the quality of patient care.

For facilities treating COVID-19 patients, having rapid, accurate diagnostic test results may be useful when assessing or monitoring patients for:

- **C-Reactive Protein (CRP)**
  Levels may be elevated in COVID-19 cases, especially severe cases.[2-15]
- **Liver, Kidney and Cardiac function**
  Elevated levels of the following biomarkers may be indicators of COVID-19 severity:[16-27]
  - Alanine Aminotransferase (ALT)[16,17,20-27]
  - Albumin (ALB)[16,19-22,25-27]
  - Aspartate Aminotransferase (AST)[16,17,19-21,23-26]
  - Creatine Kinase (CK)[16,18,20,22-24]
  - Creatinine (CREAT)[16,22,23,25,27]
  - Total Bilirubin (TBILI)[16,20,25,27]



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KEY PICCOLO XPRESS PANELS.

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As an intended point-of-care (POC) designated test with a 10 min processing time, CareStart COVID-19 Antigen Test allows effective screening of COVID-19 infection on a large scale. Rapid results within 10 minutes. Identify acute infection with 88.4% sensitivity and 100% specificty. FDA & EUA approved!



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From BioFire

SARS-CoV-2 is everyone's top suspect, but many other respiratory bugs can cause similar, overlapping symptoms. In your clinic, you can test for 19 common respiratory pathogens, including SARS- CoV-2, with the BioFire RP2.1-EZ Panel (EUA)[1]—now available under an FDA Emergency Use Authorization. Syndromic testing means all it takes is one test and just 45 minutes to round up SARS-CoV-2—and all the other usual respiratory suspects.

1. This test is not FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories.

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FIRST EUA POINT-OF-CARE (POC/WAIVED/ FINGERSTICK) COVID-19 ANTIBODY TEST NOW AVAILABLE

From Carolina Liquid Chemistries

The Fastep® COVID-19 IgG/IgM Rapid Test Device by Assure Tech., distributed in the USA by Carolina Liquid Chemistries, has received FDA Emergency Use Authorization for use with fingerstick whole blood specimens at the point-of-care, i.e. in patient care settings operating under CLIA Certificate of Waiver such as doctor's offices, hospitals, urgent care centers and emergency rooms rather than having to be sent to a central lab.Refer to carolinachemistries.com for instructions for use, fact sheets, FDA EUA letters, clinical performance studies, and material safety data sheets. Not FDA cleared; only for emergency use under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless authorization is terminated or revoked.

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2

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3

9028

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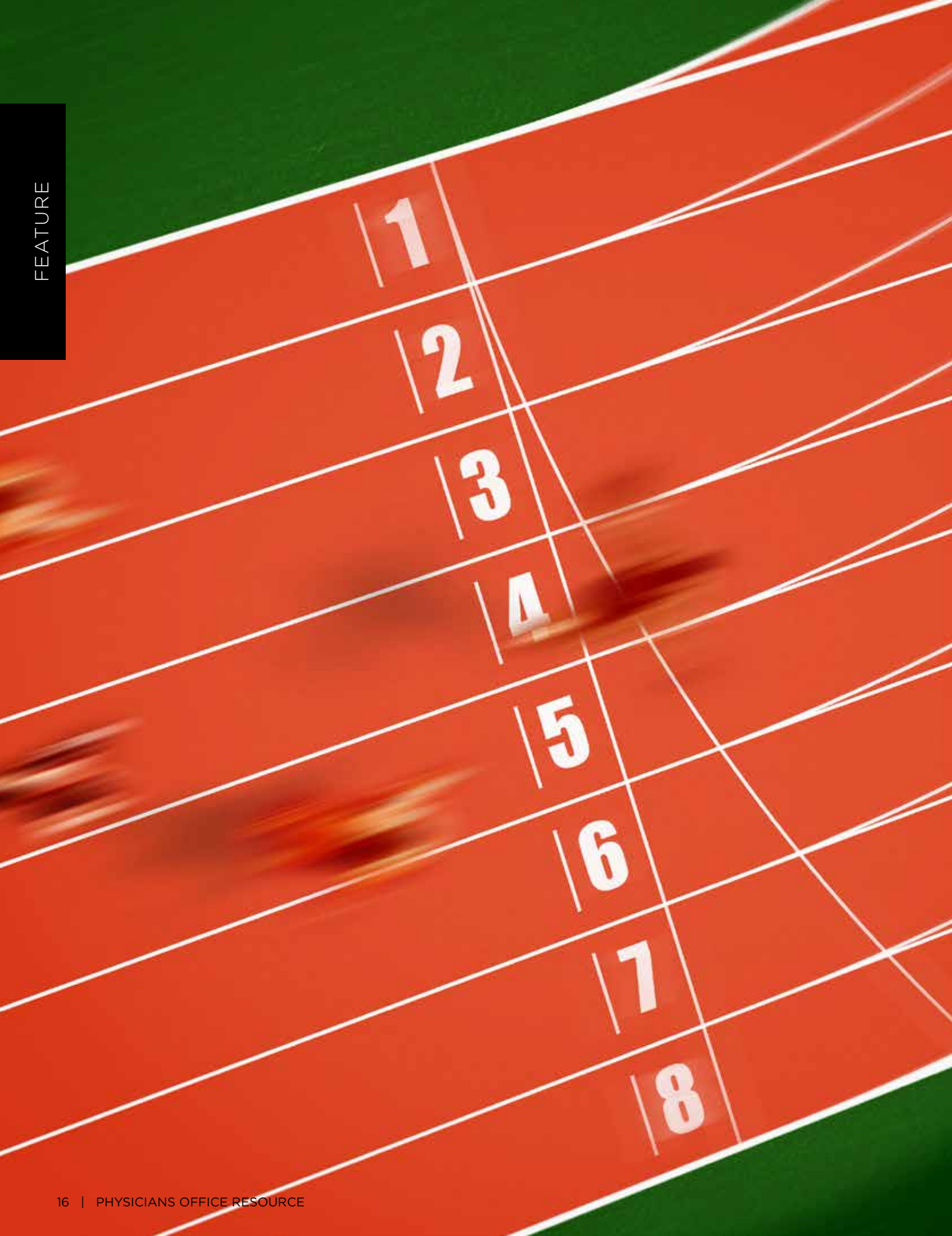
- Medicare mandates yearly cognitive assessment
- Takes 10-15 minutes to prep patient, 20 minutes to test
- Analyzes: brain health (EEG), brain processing speed (Evoke Potentials), heart health (EKG), mental health (neuropsychology)
- Reimburses using 6 CPT codes, National Average = $750 - $1000 per test
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- Easy to understand biomarkers facilitate more informed medical interventions, such as biofeedback

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The Race to Vaccinate:

COMPARING THE COVID-19 VACCINES

BY AARON MEDARIS, PHYSICIANS OFFICE RESOURCE, PUBLISHER

Editor's Note: At the time of this article was written, the FDA had authorized and recommended two vaccines for emergency use in the United States, the Pfizer-BioNTech COVID-19 vaccine and the Modern COVID-19 vaccine. Several other COVID-19 vaccines such as Johnson & Johnson, AstraZeneca, and Novavax are close to completing phase three trials.

After more than a year of dealing with the horrible effects of the COVID-19 pandemic, we now find ourselves in a race to vaccinate the world. In this article, we'll take a closer look at each vaccine currently approved along with the three that are closest to receiving their emergency use authorization; to better understand how they work, how they are administered, their effectiveness, possible side effects, and storage requirements.

For us to better understand each vaccine, let's first take a look at the three main types of vaccines being utilized to combat COVID-19: mRNA, protein subunit, and vector vaccines.

mRNA Vaccines

Messenger RNA (mRNA) vaccines are a new approach to protect us against infectious disease. They contain material from the virus that causes COVID-19, that materials give our cells instructions how to make a harmless protein that is unique to the COVID-19 virus, known as the "spike protein." Our cells then make copies of that protein and destroy the genetic material from the vaccine. In response our bodies build T-lymphocytes and B-lymphocytes that remember how to fight the virus that causes COVID-19 as a protection against future infections.

Protein Subunit Vaccines

Protein subunit vaccines include pieces of harmless virus proteins that cause COVID-19. This causes an immune response and the body begins to take T-lymphocytes and antibodies. If a future COVID-19 infection occurs, memory cells will be able to recognize and fight the virus.

Vector Vaccines

Vector vaccines contain a weakened version of a live virus. This "weakened version" is a different and harmless virus other than COVID-19, however it contains genetic material from the COVID-19 virus, called a viral vector. Once the viral vector is inside our cells, our body begins to manufacture a harmless piece of the virus that causes COVID-19. This piece is known as a spike protein and it is only found on the surface of the COVID-19 virus. Our immune system recognizes that this spike does not belong there and begins to produce T-lymphocytes and B-lymphocytes that will fight the virus and remember how to fight in the future.

Current Emergency Use Authorized Vaccines in the Fight to End COVID-19 Pandemic

Pfizer-BioNTech COVID-19 Vaccine

The Pfizer-BioNTech COVID-19 Vaccine, BNT162b2, was approved on December 11, 2020 and utilizes mRNA technology to fight COVID-19. This vaccine shows 95% effectiveness against the virus and requires two doses three weeks apart. Possible side effects can happen within 7 days of being vacci-

nated and can include fatigue, headache, chills, and muscle pain especially after the second dose. This vaccine is recommended for people 16 years of age and older. However, people with a history of serious allergic reactions including reactions to vaccine ingredients should not be vaccinated. Regarding women who are pregnant and breastfeeding, limited data is available. For the most up to date recommendations and insights, please visit: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html. This vaccine has three options for storage: 1. Ultra-low-temperature freezer. 2. The Pfizer thermal shippers, in which the doses will arrive in, can be used as temporary storage units by refilling them with dry ice every five days for up to 30 days. 3. Refrigeration units that are commonly available in hospitals can be used to store the vaccine for five days at 2-8°C. Once thawed and stored under 2-8°C conditions, the vials cannot be re-frozen or stored under frozen conditions.

Moderna COVID-19 Vaccine
Moderna COVID-19 Vaccine, mRNA-1273 was approved on December 18, 2020 and like the Pfizer-BioNTech vaccine utilizes mRNA technology. It has shown to be 94.1% effective at protecting people from getting the virus and requires two doses four weeks apart. Possible side effects can include fever, muscle aches, and headaches. Side effects tend to be worse after the second dose. This vaccine is recommended for people over 18 years old. Like most vaccines, people with a history of serious allergic reactions including reactions to vaccine ingredients should not be vaccinated. Regarding women who are pregnant and breastfeeding, limited data is available. For the most up to date recommendations and insights, please visit: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html . This vaccine is stored frozen between -25 to -15°C. It can be stored refrigerated between 2-8°C for up to 30 days prior to first use but cannot be refroze once thawed.

Other Vaccines Working Towards Receiving EUA

Oxford-AstraZeneca COVID-19 Vaccine
The Oxford-AstraZeneca COVID-19 vaccine utilizes a common cold viral vector to deliver the code that allows our cells to make the SARS-CoV-2 spike protein. As of early February 2021, this vaccine is still in Phase 3 clinical trials, but is could submit for EUA in late March. Initial findings show that this vaccine is 70% effective after two doses four weeks apart. Side effects can include injection site pain, fever, muscle aches, and headaches. Because this vaccine is still in Phase 3 trials, no further information is given regarding who this vaccine is recommended for and who should not get it. For the most up to date information about the progress of this and other vaccines you can visit clinicaltrials.gov.

"Within the next couple of months our arsenal of vaccines will increase and even though the viral vector and protein subunit vaccines may not be as effective in preventing COVID-19, they have been extremely effective in preventing serious complications, hospitalization, and death."

Johnson & Johnson COVID-19 Vaccine
Janssen Pharmeceutica, a division of Johnson & Johnson is developing this vaccine in collaboration with Beth Israel Deaconess Medical Center. The Johnson & Johnson vaccine utilizes a viral vector to deliver the double stranded DNA genetic code that allows our cells to make the SARS-CoV-2 spike protein. On February 5, 2021 they submitted application for emergency use authorization (EUA). Clinical trials showed that after a single dose, this vaccine is 66% effective in protecting people from getting infected. 66% may seem like quite a drop from the 95% and 94% of Pfizer and Moderna, but it was 85% effective at preventing serious complications due to COVID-19. Johnson & Johnson also reported that the only hospitalizations and deaths that occurred in their trails were those within the placebo group. Other advantages include a single dose and basic refrigeration.

Novavax COVID-19 Vaccine
The Novavax COVID-19 vaccine, NVX-CoV2373 utilizes a protein subunit mechanism to fight against the COVID-19 virus. As of early February 2021, this vaccine is still in phase 3 trials and has not applied for EUA with the FDA. Current efficacy against the COVID-19 virus is at 89.3% with two doses administered 21 days apart. Side effects can include pain and tenderness at injection site, fatigue, headaches, and muscle aches. Only basic refrigeration is required for storage.

The Race to Vaccinate
We've all head President Joe Biden's goal or 100 million vaccine doses in the first 100 days of his presidency. When you realize that would require 1 million doses every day for 100 days to hit that mark – the goal to many seems quite out of reach. However, research shows we're not far off with somewhere between 800,000-900,000 doses per day and all of that is being done with only two approved vaccines.

Within the next couple of months our arsenal of vaccines will increase and even though the viral vector and protein subunit vaccines may not be as effective in preventing COVID-19, they have been extremely effective in preventing serious complications, hospitalization, and death. Not to mention they provide a less expensive option with easier shipping and storage requirements. These qualities will not only help the US reach is vaccination goals, but will play an essential role in controlling the virus worldwide.

Let us help you make COVID-19 testing and daily compliant reporting to state and federal agencies easy!

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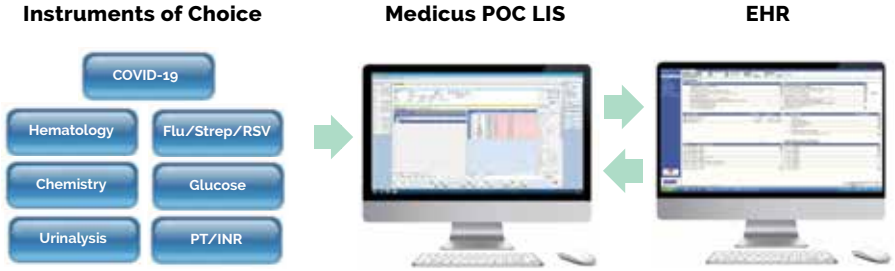
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The BD Veritor™ Plus System is a portable, easy-to-use, testing solution for SARS-COV-2*, Flu A+ B and other respiratory tract infections that delivers results in 15 minutes or less. It features two analysis modes that adapt to your workflow, online education tools, and optional reporting capabilities including the BD Synapsys™ Informatics Solution—making it the point-of-care diagnostic tool you won't want to be without.

*EUA authorized by FDA

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From Point of Care at Abbott

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For intended use and complete product information, visit pointof-care.abbott.

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CELL-DYN EMERALD HEMATOLOGY ANALYZER

From Abbott

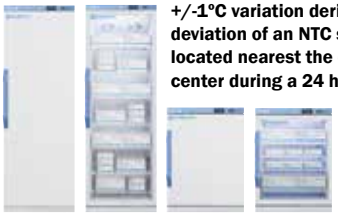
CELL-DYN Emerald is a 3-part differential hematology analyzer that offers high performance in an affordable, compact design that provides reliable and accurate patient results every time. As a smaller operating laboratory, you need a solution that offers reliable results. CELL-DYN Emerald provides results in under 65 seconds. CELL-DYN Emereald's small size, simple touch screen software and reliability offer an easy-to-use, truly compact table/bench top instrument for easy performance in your laboratory.

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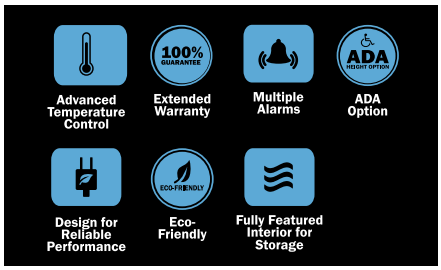


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Accucold	Capacity	Height	Width	Depth	Door	PRICE
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ARG1PV	1 cu.ft.	21.5"	17.5"	20"	Glass	**820.00**
ARS3PV	3 cu.ft.	33.75"	18.5"	19"	White	**884.00**
ARG3PV	3 cu.ft.	33.75"	18.5"	19.5"	Glass	**897.00**
ARS6PV	6 cu.ft.	32.5"	23.5"	24.5"	White	**996.00**
ARG6PV	6 cu.ft.	32.5"	23.5"	25"	Glass	**1,010.00**
ARS8PV	8 cu.ft.	50"	23.38"	24.5"	White	**1,218.00**
ARG8PV	8 cu.ft.	50"	23.38"	25"	Glass	**1,287.00**
ARS12PV	12 cu.ft.	61.75"	23.38"	24.5"	White	**1,690.00**
ARG12PV	12 cu.ft.	61.75"	23.38"	25"	Glass	**1,704.00**
ARS15PV	15 cu.ft.	72"	23.5"	24.5"	White	**1,866.00**
ARG15PV	15 cu.ft.	72"	23.5"	25"	Glass	**1,879.00**

models with data loggers are available

Pharma-Lab Refrigerators

Accucold	Capacity	Height	Width	Depth	Door	PRICE
ARS23ML	23 cu.ft.	83.75	27.5	31	(1) Stainless	**2,311.00**
ARG23ML	23 cu.ft.	83.75	27.5	31	(1) Glass	**2,633.00**
ARS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	**3,503.00**
ARG49ML	49 cu.ft.	83.75	55.25	31	(2) Glass	**4,037.00**

Pharma-Lab Freezers

Accucold	Capacity	Height	Width	Depth	Door	PRICE
AFS23ML	23 cu.ft.	83.75	27.5	31	(1) Stainless	**2,633.00**
AFS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	**4,037.00**

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Public Vaccine _____

Private Vaccine + _____

Total doses = _____

Multiply (max inventory) x 1.25

Maximum doses = _____

2 Match your maximum doses with the minimum cubic feet needed to safely store your vaccine

Max. Doses	Minimum Cubic Ft.
2,000+ doses	may need more than one refrigerator
1000-2000	40 cu.ft
900-1000	36 cu.ft
801-900	21-23 cu.ft
701-800	17-19.5 cu.ft
400-700	11-16.7 cu.ft
100-399	4.9-6.1 cu.ft

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Quality Management of Point of Care Testing

BY IRWIN Z. ROTHENBERG, MBA, MS, CLS(ASCP)

With emerging technological innovations in healthcare, including smartphone apps, biosensors, lab-on-a chip, and wearable devices—all of which offer a closer connection to the patient—point-of-care (POC) technologies are quickly becoming part of the transformation of the healthcare landscape. The driving concept in support of point-of-care testing (POCT) is to bring testing closer to the patient and results conveniently and quickly to the provider to expedite diagnosis and subsequent treatment. POCT allows for faster clinical decisions in hospitals, physicians' offices, ambulances, patient homes, and in the field.

The College of American Pathologists (CAP) defines POCT as "testing that is performed near or at the site of a patient with the result leading to a possible change in the care of the patient."

POCT's popularity has risen in recent years due to its convenience, timeliness, and potential to improve patient outcomes. In fact, POCT is estimated to be increasing at 10-12% annually, compared to a 6-7% annual increase for other clinical laboratory testing. Used appropriately, POCT can be a key component in meeting the goals of simultaneously improving patient outcomes and reducing healthcare costs.

Hundreds of tests once considered too complex for POCT are now routinely performed outside the laboratory. Sensor technologies enable the rapid analysis of blood samples for many critical care assays, includingi :

Blood gases/electrolytes
Cardiac markers
Cholesterol/lipids
Coagulation monitoring (INR; ACT, Heparin; Hemostasis Assessment)
Drugs of abuse testing (DOA)
Fecal occult blood
Glucose monitoring; Hemoglobin A1C

Hematology
Infectious diseases (such as Influenza and Rapid Strep)
Pregnancy and fertility
Tumor/cancer markers
Urinalysis testing
Other Chemistries (Magnesium, Lactate, Micro-albumin, Creatinine)
D-dimer for thromboembolism

Challenges inherent in managing point of care testing:

In the core lab, errors occur most frequently in the pre- and post-analytic phases, however, POCT errors occur primarily in the analytic phase of testing. This is related to a lack of understanding or training of non-laboratory staff who are involved in POCT. In addition,
there are possible test limitations and misuse in a particular environment. This often raises concern over the reliability of test results.

More than ever, the laboratory must be proactive in monitoring all aspects of POCT, if quality care is to be maintained. These actions include:

- All Point of Care (POC) testing personnel must be properly trained, and have their competency periodically assessed, even if all their testing is waived
- All instruments involved should be used in accordance with manufacturer's requirements with quality control, calibration, and maintenance records monitored;
- Test results must be verified as to accuracy and (if previously patient tested) consistent with a patient's history
- Reagent storage and handling must be monitored
- Utilization of split sampling and proficiency testing is recommended for monitoring quality.

Managing POCT: The Laboratory Liaison

Mindful that POC testing may be performed by non-laboratory staff, laboratories often have a staff tech responsible for monitoring this testing, acting as both a liaison, as well as a technical resource for the POC testing staff.

This is an important responsibility, as feedback from the field to the laboratory is needed to identify potential communication problems, complaints, and the needs of both patients and staff.

The bottom line is that there should be no difference in the quality of patient care provided by the laboratory, whether performed within the confines of the laboratory itself, or anywhere else. Ultimate responsibility lies with the laboratory administration and staff.

An alternative model: POCT Management Teams[iv]

Interdisciplinary POC management teams that include the laboratory, physicians, and nurses are considered as the most effective way to ensure the best oversight. This model increases the probability of inter-departmental cooperation and buy-in by non-lab staff of all the procedures required to assure quality POCT. They would be responsible for:

- Determining the test menu
- Selecting methodologies
- Establishing policies and procedures
- Confirming proper training and competency assessment
- Overseeing regulatory compliance
- Documenting corrective action where necessary
- Providing advisory assistance to the users of POC technologies

However, regulatory standards hold the Laboratory Director ultimately responsible for managing and supervising POCT

Compliance strategies in the digital age: The Use of Data Management Systems[v]

Technology has now enabled us to monitor all aspects of POCT remotely, from test requests to test results; from QC to maintenance records to documentation of competency to operate instruments. When possible, use digitalized monitoring to ensure quality work. Here is a sampling of the capabilities of remote monitoring:

Training & Competency Assessments

- Documentation of the initial training, as required by CLIA and Accreditation organizations, prior to POC testing, followed by documented competency assessments at specific intervals.

Quality and Compliance

- QC limits and frequency intervals can be configured on the test instrument or managed remotely through a data management system.
- Data systems can prevent an operator from using the instrument once the QC interval has been exceeded or the result is not within acceptable limits.
- QC results for each test instrument and operator can be reviewed and evaluated remotely by laboratory personnel
- Documentation of comments describing corrective action for unacceptable QC results
- Some data management systems allow incorporation of manual QC results.

Instrument Use

- Monitoring instrument use through access control and electronic communication with a laboratory information system (LIS) or other network system. This communication also allows the LIS to download quality control and patient results.
- POC testing can be set up and configured remotely from a single central location with software updates manually or automatically downloaded to the instruments.
- The data management system can serve as a repository for testing locations, instrument serial numbers, and instrument service history and software versions.
- The data management system can also track the status of the connected test instruments so that communication and con nectivity issues can be addressed promptly.

POCT Operator Management

- Access to a POCT device can be authorized via operator

list downloads when the instrument queries the data management system to determine whether a particular operator is authorized.
- If an unauthorized operator attempts to use the POCT instrument, he or she will be locked out, preventing use.

Data Monitoring
- In order to comply with accreditation standards, POCT co ordinators can monitor data from activities such as correlation testing, linearity and analytical measurement range verification, proficiency testing, calibration, and patient identification.
- Data systems can automatically capture this data and document it for review. This data also can be entered by hand from manual tests (e.g. fecal occult blood, dipstick urine, pregnancy tests as well.

Inventory Management
- Reagent and control lot numbers, and established QC ranges, can be entered into the data system and uploaded to the POCT instruments.
- Alarms can be set to alert the POCT coordinator when new lots are in use that may require validation
- Many POCT devices include barcode scanning capabilities that allow reagents and controls to be scanned by operators to verify the current lot number and prevent use of expired or un-validated reagents.
- The current lot numbers may reside in the data management system.

Remote Access
- Enables POCT data management from any computers within or outside of the organization, based on how the system is configured.

Note: to ensure quality management of POCT results, and earn the confidence of the medical staff, each of these activities must be continuously monitored, whether accomplished manually, or through the use of data management systems.

Summary

Technological advances have resulted in an explosion in the number of tests that can be performed outside the laboratory setting; locations include operating rooms, nursing homes, the workplace, private homes, retail settings, and remote field sites. More than ever, the laboratory must be proactive in monitoring this, if quality care is to be maintained.

This means that all Point of Care (POC) testing personnel must be properly trained (and the training documented), have their competency periodically assessed, even if all their testing is waived; all instruments involved should be used in accordance with manufacturer's requirements with quality control, calibration, and maintenance records monitored; and test results verified as to accuracy and (if the patient has been previously tested) consistent with a patient's history. Monitor reagent storage and handling as well. Recommended is the utilization of split sampling as well as proficiency testing, as part of Good Laboratory Practice.

"...there should be no difference in the quality of patient care provided by the laboratory, whether performed within the confines of the laboratory itself, or anywhere else."

Many laboratories, mindful that POC testing may be performed by non-laboratory staff, often have a staff tech responsible for monitoring this testing, acting as both a liaison to the laboratory as well as a technical resource for the POC testing staff. The alternative is the utilization of POCT Management Teams.

The bottom line is that there should be no difference in the quality of patient care provided by the laboratory, whether performed within the confines of the laboratory itself, or anywhere else. Ultimate responsibility lies with the laboratory administration and staff.

Irwin Z. Rothenberg is a Technical Writer/Quality Advisor for COLA's Educational subsidiary, COLA Resources, Inc. (CRI), a leader in online continuing education for physicians, laboratory personnel, and allied health professionals. CRI offers continuing education through online courses, informational products in both electronic and hard copy form, webinars on cutting-edge technology and regulatory issues, and CRI on-site Symposia for Clinical Laboratories, providing live educational sessions and interactive workshops with leading industry organizations. For more information, visit their website at www.criedu.org or call 1-800-981-9883.

Endnotes

1 Futrell, K. Laboratory Point of Care Testing: A Future Outlook. POCT Progression and the Importance of Connectivity Orchard Software Whitepaper. June 2015. http://www.orchardsoft.com/files/white_paper_lab_poc_testing.pdf

2 Futrell, K. POCT: POCT Supports New Demands. Changes in healthcare open door for point-of-care testing to improve outcomes. December 9, 2013. http://laboratory-manager.advanceweb.com/Archives/Article-Archives/POCT-POCT-Supports-New-Demands.aspx

3 Camacho-Ryan, O., Belthof, RL. Monitoring Point of Care Testing Compliance. Clinical Laboratory News. February 1, 2016. https://www.aacc.org/publications/cln/articles/2016/february/monitoring-point-of-care-testing-compliance

Now Approved FOR PATIENTS WITH **ASTHMA** AGED 18 AND OLDER

TRELEGY: The first and only once-daily triple therapy in a single inhaler for adult patients with COPD or ASTHMA

FOR COPD



TRELEGY
100/62.5/25 mcg

FOR ASTHMA



TRELEGY
100/62.5/25 mcg

AND



TRELEGY
200/62.5/25 mcg

INDICATIONS

- COPD: TRELEGY 100/62.5/25 mcg is for maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).
- Asthma: TRELEGY is indicated for the maintenance treatment of asthma in patients aged 18 years and older.

Limitations of Use: TRELEGY is NOT indicated for the relief of acute bronchospasm.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

TRELEGY is contraindicated in the following:

- Primary treatment of status asthmaticus or other acute episodes of COPD or asthma where intensive measures are required.
- Patients with severe hypersensitivity to milk proteins or demonstrated hypersensitivity to fluticasone furoate (FF), umeclidinium (UMEC), vilanterol (VI), or any of the excipients.

WARNINGS AND PRECAUTIONS

- Long-acting beta$_2$-adrenergic agonist (LABA) monotherapy for asthma increases the risk of asthma-related death, and in pediatric and adolescent patients, available data also suggest an increased risk of asthma-related hospitalization. These findings are considered a class effect of LABA monotherapy. When LABA are used in fixed-dose combination with inhaled corticosteroids (ICS), data from large clinical trials do not show a significant increase in the risk of serious asthma-related events (hospitalizations, intubations, death) compared with ICS alone. TRELEGY is not indicated for use in pediatric patients aged 17 years and younger.
- TRELEGY should NOT be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD or asthma.
- TRELEGY is NOT a rescue medication and should NOT be used for the relief of acute bronchospasm or symptoms. Acute symptoms should be treated with an inhaled, short-acting beta$_2$-agonist.
- TRELEGY should not be used more often or at higher doses than recommended or with another LABA for any reason, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs, like LABA.
- Oropharyngeal candidiasis has occurred in patients treated with orally inhaled drug products containing fluticasone furoate. Advise patients to rinse their mouths with water without swallowing after inhalation.
- Lower respiratory tract infections, including pneumonia, have been reported following use of ICS, like fluticasone furoate. Physicians should remain vigilant for the possible development of pneumonia in patients with COPD, as clinical features of pneumonia and exacerbations frequently overlap.
- A more serious or even fatal course of chickenpox or measles may occur in susceptible patients using corticosteroids. ICS should be used with caution, if at all, in patients with active or quiescent tuberculosis infections of the respiratory tract; systemic fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex.

Please see additional Important Safety Information for TRELEGY throughout.
Please see Brief Summary of Prescribing Information for TRELEGY following this ad.

gsk | INNOVIVA

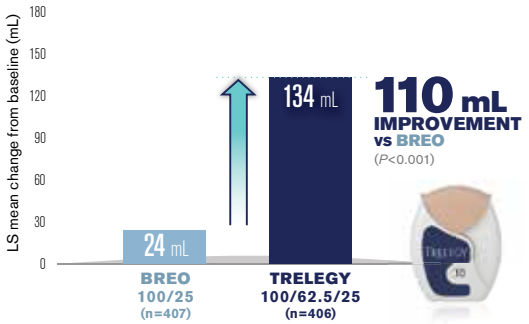
TRELEGY ELLIPTA
(fluticasone furoate 100 mcg, umeclidinium 62.5 mcg, and vilanterol 25 mcg inhalation powder)

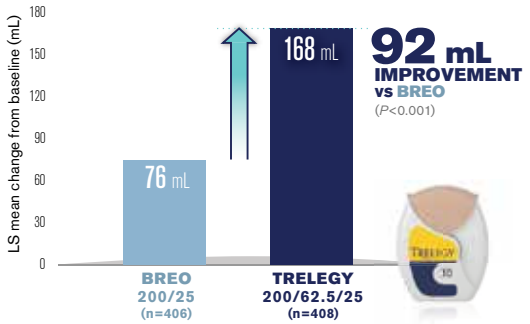
TRELEGY—SIGNIFICANT lung function improvement for patients with ASTHMA

FOR ADULT PATIENTS WITH ASTHMA

In a 24- to 52-week study vs BREO, an ICS/LABA[1]

PRIMARY ENDPOINT: CHANGE FROM BASELINE IN TROUGH FEV_1 AT WEEK 24





CAPTAIN STUDY DESCRIPTION[1]

Design: 24- to 52-week, randomized, double-blind, active-controlled, parallel-group, multicenter study that evaluated the safety and efficacy of TRELEGY 100/62.5/25 and TRELEGY 200/62.5/25 compared with BREO 100/25 and BREO 200/25, respectively (each administered once daily in the morning).

Patients: Patients ≥18 years were eligible if they had inadequately controlled asthma (ie, ACQ-6 score ≥1.5) while receiving daily ICS/LABA (ICS dose >250 mcg FP or equivalent) for ≥12 weeks pre-study. After a 5-week run-in and stabilization period, 2436 patients were randomized to treatment (mean age 53 years, baseline mean percent predicted FEV_1 68%).

ACQ-6=Asthma Control Questionnaire 6; FP=fluticasone propionate.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- Particular care is needed for patients transferred from systemic corticosteroids to ICS because deaths due to adrenal insufficiency have occurred in patients during and after transfer. Taper patients slowly from systemic corticosteroids if transferring to TRELEGY.
- Hypercorticism and adrenal suppression may occur with higher than the recommended dosage or at the regular dosage of ICS in susceptible individuals. If such changes occur, reduce the dose of TRELEGY slowly and consider other treatments for management of COPD or asthma symptoms.
- Caution should be exercised when considering the coadministration of TRELEGY with ketoconazole and other known strong CYP3A4 inhibitors (including, but not limited to, ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleandomycin, voriconazole) because increased systemic corticosteroid and cardiovascular adverse effects may occur.
- If paradoxical bronchospasm occurs, discontinue TRELEGY and institute alternative therapy.
- Hypersensitivity reactions such as anaphylaxis, angioedema, rash, and urticaria may occur after administration of TRELEGY. Discontinue TRELEGY if such reactions occur.
- Vilanterol can produce clinically significant cardiovascular effects in some patients as measured by increases in pulse rate, systolic or diastolic blood pressure, and also cardiac arrhythmias, such as supraventricular tachycardia and extrasystoles. If such effects occur, TRELEGY may need to be discontinued. TRELEGY should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.
- Decreases in bone mineral density have been observed with long-term administration of products containing ICS. Patients with major risk factors for decreased bone mineral content, such as prolonged immobilization, family history of osteoporosis, postmenopausal status, tobacco use, advanced age, poor nutrition, or chronic use of drugs that can reduce bone mass (eg, anticonvulsants, oral corticosteroids) should be monitored and treated with established standards of care prior to initiating TRELEGY and periodically thereafter.
- Glaucoma, increased intraocular pressure, and cataracts have been reported following the long-term administration of ICS or inhaled anticholinergics. Consider referral to an ophthalmologist in patients who develop ocular symptoms or use TRELEGY long term.
- Use with caution in patients with narrow-angle glaucoma. Instruct patients to contact a healthcare provider immediately if signs or symptoms of acute narrow-angle glaucoma develop.
- Use with caution in patients with urinary retention, especially in patients with prostatic hyperplasia or bladder-neck obstruction. Instruct patients to contact a healthcare provider immediately if signs or symptoms of urinary retention develop.
- Use with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, and ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines.
- Be alert to hypokalemia and hyperglycemia.
- Orally inhaled corticosteroids may reduce growth velocity in children and adolescents.

ADVERSE REACTIONS: TRELEGY 100/62.5/25 MCG FOR COPD

- In subjects with COPD, the most common adverse reactions (≥1% and more common than placebo + FF/VI) reported in two 12-week clinical trials with UMEC + FF/VI, the components of TRELEGY, (and placebo + FF/VI) were: headache, 4% (3%); back pain, 4% (2%); dysgeusia, 2% (<1%); diarrhea, 2% (<1%); cough, 1% (<1%); oropharyngeal pain, 1% (0%); and gastroenteritis, 1% (0%).
- Additional adverse reactions (≥1% incidence) reported in subjects with COPD taking TRELEGY in a 52-week trial included upper respiratory tract infection, pneumonia, bronchitis, oral candidiasis, arthralgia, influenza, sinusitis, pharyngitis, rhinitis, constipation, urinary tract infection, and dysphonia.

Please see additional Important Safety Information for TRELEGY throughout.
Please see Brief Summary of Prescribing Information for TRELEGY following this ad.

TRELEGY HAS BROAD COVERAGE

Individual access may vary by geography and plan benefit design



TRELEGY is covered* for 98% of commercial and 87% of Medicare Part D patients† nationally.

*"Covered" is defined as any potential for reimbursement from a health plan and may include step edits, prior authorizations, and other restrictions. Formulary status may vary and is subject to change. Formulary coverage does not imply clinical efficacy or safety.

†"Patients" means covered lives for all commercial and employer payer types (excluding Managed Medicaid) and covered lives enrolled in Medicare payer types as calculated by Managed Markets Insight & Technology as of October 2020.

Veterans Affairs (VA) and Indian Health Service (IHS) lives have been omitted when calculating the percentage of lives for this geography.

What you need to know about this formulary information:

Individual access may vary by geography and plan benefit design.

Formulary status may vary and is subject to change. Formulary coverage does not imply clinical efficacy or safety. This is not a guarantee of partial or full coverage or payment. Consumers may be responsible for varying out-of-pocket costs based on an individual's plan and its benefit design. Each plan administrator determines actual benefits and out-of-pocket costs per its plan's policies.

Verify coverage with plan sponsor or Centers for Medicare & Medicaid Services. Medicare Part D patients may obtain coverage for products not otherwise covered or covered at a higher co-pay via the medical necessity process.

SOURCE: Data on file, GSK. Coverage for TRELEGY 200/62.5/25 mcg is anticipated to be at parity with TRELEGY 100/62.5/25 mcg.

PAY AS LITTLE AS $0‡

Maximum savings $2400/year

Eligible commercially insured/covered patients may pay as little as $0 for each covered 30-, 60-, or 90-day supply (1-3 inhalers) of TRELEGY for up to 12 months.

‡Restrictions apply. This coupon may not be used by government beneficiaries, including those eligible for or enrolled in Medicare. See full requirements and restrictions at TRELEGY.com/save

Maximum savings $2400/year

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS: TRELEGY FOR ASTHMA

- In subjects with asthma, the most common adverse reactions (≥2% incidence with TRELEGY) reported in a 24-week to 52-week clinical trial with:
  - TRELEGY 100/62.5/25 mcg (or FF/VI 100/25 mcg) were: pharyngitis/nasopharyngitis, 17% (16%); headache, 9% (7%); upper respiratory tract infection/viral upper respiratory tract infection, 5% (7%); respiratory tract infection/viral respiratory tract infection, 4% (4%); bronchitis, 4% (3%); influenza, 4% (3%); back pain, 3% (4%); sinusitis/acute sinusitis, 2% (3%); rhinitis, 2% (3%).
  - TRELEGY 200/62.5/25 mcg (or FF/VI 200/25 mcg) were: pharyngitis/nasopharyngitis, 15% (16%); upper respiratory tract infection/viral upper respiratory tract infection, 7% (6%); headache, 5% (6%); bronchitis, 5% (5%); sinusitis/acute sinusitis, 3% (2%); respiratory tract infection/viral respiratory tract infection, 3% (2%); back pain, 2% (1%); urinary tract infection, 2% (<1%).

DRUG INTERACTIONS

- TRELEGY should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval, or within 2 weeks of discontinuation of such agents, because they may potentiate the effect of vilanterol on the cardiovascular system.
- Use beta-blockers with caution, as they not only block the pulmonary effect of beta-agonists, such as vilanterol, but may produce severe bronchospasm in patients with COPD or asthma.
- Use with caution in patients taking non–potassium-sparing diuretics, as ECG changes and/or hypokalemia associated with these diuretics may worsen with concomitant beta-agonists.
- Avoid coadministration of TRELEGY with other anticholinergic-containing drugs, as this may lead to an increase in anticholinergic adverse effects.

USE IN SPECIFIC POPULATIONS

- TRELEGY is not indicated for use in children and adolescents. The safety and efficacy in pediatric patients (aged 17 years and younger) have not been established.
- Use TRELEGY with caution in patients with moderate or severe hepatic impairment, as fluticasone furoate systemic exposure may increase by up to 3-fold. Monitor for corticosteroid-related side effects.

Reference: 1. Data on file, GSK.

TRELEGY ELLIPTA was developed in collaboration with INNOVIVA

The shape of the ELLIPTA inhaler is a trademark of the GSK group of companies. Trademarks are property of their respective owners.

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FVUJRNA200003 October 2020
Produced in USA.

To learn more about TRELEGY, visit **MeetTRELEGY.com**

TRELEGY ELLIPTA
(fluticasone furoate, umeclidinium, and vilanterol inhalation powder)

BRIEF SUMMARY

TRELEGY ELLIPTA (fluticasone furoate, umeclidinium, and vilanterol inhalation powder), for oral inhalation use

The following is a brief summary only; see full prescribing information for complete product information.

1. INDICATIONS AND USAGE

1.1 Maintenance Treatment of Chronic Obstructive Pulmonary Disease

TRELEGY 100/62.5/25 mcg is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

1.2 Maintenance Treatment of Asthma

TRELEGY is indicated for the maintenance treatment of asthma in patients aged 18 years and older.

1.3 Limitations of Use

TRELEGY is NOT indicated for the relief of acute bronchospasm.

4 CONTRAINDICATIONS

TRELEGY is contraindicated in the following conditions:

- Primary treatment of status asthmaticus or other acute episodes of COPD or asthma where intensive measures are required *[see Warnings and Precautions (5.2)]*.
- Severe hypersensitivity to milk proteins or demonstrated hypersensitivity to fluticasone furoate, umeclidinium, vilanterol, or any of the excipients *[see Warnings and Precautions (5.11), Description (11) of full prescribing information]*.

5 WARNINGS AND PRECAUTIONS

5.1 Serious Asthma-Related Events – Hospitalizations, Intubations, Death

Use of long-acting beta$_2$-adrenergic agonists (LABA) as monotherapy (without ICS) for asthma is associated with an increased risk of asthma-related death. Available data from controlled clinical trials also suggest that use of LABA as monotherapy increases the risk of asthma-related hospitalization in pediatric and adolescent patients. These findings are considered a class effect of LABA monotherapy. When LABA are used in fixed-dose combination with ICS, data from large clinical trials do not show a significant increase in the risk of serious asthma-related events (hospitalizations, intubations, death) compared with ICS alone *(see Serious Asthma-Related Events With Inhaled Corticosteroid/Long-acting Beta$_2$-adrenergic Agonists)*.

Serious Asthma-Related Events With Inhaled Corticosteroid/Long-acting Beta$_2$-adrenergic Agonists

Four (4) large, 26-week, randomized, double-blind, active-controlled clinical safety trials were conducted to evaluate the risk of serious asthma-related events when LABA were used in fixed-dose combination with ICS compared with ICS alone in subjects with asthma. Three (3) trials included adult and adolescent subjects aged 12 years and older: 1 trial compared budesonide/formoterol with budesonide, 1 trial compared fluticasone propionate/salmeterol inhalation powder with fluticasone propionate inhalation powder, and 1 trial compared mometasone furoate/formoterol with mometasone furoate. The fourth trial included pediatric subjects aged 4 to 11 years and compared fluticasone propionate/salmeterol inhalation powder with fluticasone propionate inhalation powder. The primary safety endpoint for all 4 trials was serious asthma-related events (hospitalizations, intubations, death). A blinded adjudication committee determined whether events were asthma related.

The 3 adult and adolescent trials were designed to rule out a risk margin of 2.0, and the pediatric trial was designed to rule out a risk margin of 2.7. Each individual trial met its pre-specified objective and demonstrated non-inferiority of ICS/LABA to ICS alone. A meta-analysis of the 3 adult and adolescent trials did not show a significant increase in risk of a serious asthma-related event with ICS/LABA fixed-dose combination compared with ICS alone (Table 1). These trials were not designed to rule out all risk for serious asthma-related events with ICS/LABA compared with ICS.

Table 1. Meta-analysis of Serious Asthma-Related Events in Subjects with Asthma Aged 12 Years and Older

	ICS/LABA (n = 17,537)[a]	ICS (n = 17,552)[a]	ICS/LABA vs. ICS Hazard Ratio (95% CI)[b]
Serious asthma-related event[c]	116	105	1.10 (0.85, 1.44)
Asthma-related death	2	0	
Asthma-related intubation (endotracheal)	1	2	
Asthma-related hospitalization (≥24-hour stay)	115	105	

ICS = Inhaled Corticosteroid, LABA = Long-acting Beta$_2$-adrenergic Agonist.

[a] Randomized subjects who had taken at least 1 dose of study drug. Planned treatment used for analysis.

[b] Estimated using a Cox proportional hazards model for time to first event with baseline hazards stratified by each of the 3 trials.

[c] Number of subjects with event that occurred within 6 months after the first use of study drug or 7 days after the last date of study drug, whichever date was later. Subjects can have 1 or more events, but only the first event was counted for analysis. A single, blinded, independent adjudication committee determined whether events were asthma related.

The pediatric safety trial included 6,208 pediatric subjects aged 4 to 11 years who received ICS/LABA (fluticasone propionate/salmeterol inhalation powder) or ICS (fluticasone propionate inhalation powder). In this trial, 27/3,107 (0.9%) subjects randomized to ICS/LABA and 21/3,101 (0.7%) subjects randomized to ICS experienced a serious asthma-related event. There were no asthma-related deaths or intubations. ICS/LABA did not show a significantly increased risk of a serious asthma-related event compared with ICS based on the pre-specified risk margin (2.7), with an estimated hazard ratio of time to first event of 1.29 (95% CI: 0.73, 2.27). TRELEGY is not indicated for use in pediatric patients aged 17 years and younger.

Salmeterol Multicenter Asthma Research Trial (SMART)

A 28-week, placebo-controlled, U.S. trial that compared the safety of salmeterol with placebo, each added to usual asthma therapy, showed an increase in asthma-related deaths in subjects receiving salmeterol (13/13,176 in subjects treated with salmeterol versus 3/13,179 in subjects treated with placebo; relative risk: 4.37 [95% CI: 1.25, 15.34]). Use of background ICS was not required in SMART. The increased risk of asthma-related death is considered a class effect of LABA monotherapy.

5.2 Deterioration of Disease and Acute Episodes

TRELEGY should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD or asthma. TRELEGY has not been studied in subjects with acutely deteriorating COPD or asthma. The initiation of TRELEGY in this setting is not appropriate.

If TRELEGY 100/62.5/25 mcg no longer controls symptoms of bronchoconstriction; the patient's inhaled, short-acting beta$_2$-agonist becomes less effective; or the patient needs more short-acting beta$_2$-agonist than usual, these may be markers of deterioration of disease. In this setting, re-evaluate the patient and the COPD treatment regimen at once. For COPD, the daily dose of TRELEGY 100/62.5/25 mcg should not be increased.

Increasing use of inhaled, short-acting beta$_2$-agonists is a marker of deteriorating asthma. In this situation, the patient requires immediate reevaluation with reassessment of the treatment regimen, giving special consideration to the need for additional therapeutic options. Patients should not use more than 1 inhalation once daily of TRELEGY.

TRELEGY should not be used for the relief of acute symptoms, ie, as rescue therapy for the treatment of acute episodes of bronchospasm. TRELEGY has not been studied in the relief of acute symptoms and extra doses should not be used for that purpose. Acute symptoms should be treated with an inhaled, short-acting beta$_2$-agonist.

When beginning treatment with TRELEGY, patients who have been taking oral or inhaled, short-acting beta$_2$-agonists on a regular basis (eg, 4 times a day) should be instructed to discontinue the regular use of these drugs and to use them only for symptomatic relief of acute respiratory symptoms. When prescribing TRELEGY, the healthcare provider should also prescribe an inhaled, short-acting beta$_2$-agonist and instruct the patient on how it should be used.

Continued on next page

5.3 Avoid Excessive Use of TRELEGY and Avoid Use with Other Long-acting Beta$_2$-agonists

TRELEGY should not be used more often than recommended, at higher doses than recommended, or in conjunction with other therapies containing LABA, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Patients using TRELEGY should not use another therapy containing a LABA (eg, salmeterol, formoterol fumarate, arformoterol tartrate, indacaterol) for any reason.

5.4 Oropharyngeal Candidiasis

TRELEGY contains fluticasone furoate, an ICS. Localized infections of the mouth and pharynx with *Candida albicans* have occurred in subjects treated with orally inhaled drug products containing fluticasone furoate. When such an infection develops, it should be treated with appropriate local or systemic (ie, oral) antifungal therapy while treatment with TRELEGY continues. In some cases, therapy with TRELEGY may need to be interrupted. Advise the patient to rinse his/her mouth with water without swallowing following administration of TRELEGY to help reduce the risk of oropharyngeal candidiasis.

5.5 Pneumonia

Lower respiratory tract infections, including pneumonia, have been reported following the inhaled administration of corticosteroids.

Physicians should remain vigilant for the possible development of pneumonia in patients with COPD as clinical features of pneumonia and exacerbations frequently overlap.

In two 12-week trials of subjects with COPD (N = 824), the incidence of pneumonia was <1% for both treatment arms: umeclidinium 62.5 mcg + fluticasone furoate/vilanterol 100/25 mcg or placebo + fluticasone furoate/vilanterol 100/25 mcg. Fatal pneumonia occurred in 1 subject receiving placebo + fluticasone furoate/vilanterol 100/25 mcg.

In a 52-week trial of subjects with COPD (N = 10,355), the incidence of pneumonia was 8% for TRELEGY 100/62.5/25 mcg (n = 4,151), 7% for fluticasone furoate/vilanterol 100/25 mcg (n = 4,134), and 5% for umeclidinium/vilanterol 62.5/25 mcg (n = 2,070). Fatal pneumonia occurred in 12 of 4,151 patients (0.35 per 100 patient-years) receiving TRELEGY 100/62.5/25 mcg; 5 of 4,134 patients (0.17 per 100 patient-years) receiving fluticasone furoate/vilanterol 100/25 mcg; and 5 of 2,070 patients (0.29 per 100 patient-years) receiving umeclidinium/vilanterol 62.5/25 mcg.

In a mortality trial with fluticasone furoate/vilanterol 100/25 mcg with a median treatment duration of 1.5 years in 16,568 subjects with moderate COPD and cardiovascular disease, the annualized incidence rate of pneumonia was 3.4 per 100 patient-years for fluticasone furoate/vilanterol 100/25 mcg, 3.2 for placebo, 3.3 for fluticasone furoate 100 mcg, and 2.3 for vilanterol 25 mcg. Adjudicated, on-treatment deaths due to pneumonia occurred in 13 subjects receiving fluticasone furoate/vilanterol 100/25 mcg, 9 subjects receiving placebo, 10 subjects receiving fluticasone furoate 100 mcg, and 6 subjects receiving vilanterol 25 mcg (<0.2 per 100 patient-years for each treatment group).

5.6 Immunosuppression and Risk of Infections

Chickenpox and measles can have a more serious or even fatal course in susceptible children or adults using corticosteroids. In such children or adults who have not had these diseases or been properly immunized, particular care should be taken to avoid exposure. How the dose, route, and duration of corticosteroid administration affect the risk of developing a disseminated infection is not known. The contribution of the underlying disease and/or prior corticosteroid treatment to the risk is also not known. If a patient is exposed to chickenpox, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated. If a patient is exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IG) may be indicated. (See the respective package inserts for complete VZIG and IG prescribing information.) If chickenpox develops, treatment with antiviral agents may be considered.

ICS should be used with caution, if at all, in patients with active or quiescent tuberculosis infections of the respiratory tract; systemic fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex.

5.7 Transferring Patients From Systemic Corticosteroid Therapy

HPA Suppression/Adrenal Insufficiency

Particular care is needed for patients who have been transferred from systemically active corticosteroids to ICS because deaths due to adrenal insufficiency have occurred in patients during and after transfer from systemic corticosteroids to less systemically available ICS. After withdrawal from systemic corticosteroids, a number of months are required for recovery of hypothalamic-pituitary-adrenal (HPA) function.

Patients who have been previously maintained on 20 mg or more of prednisone (or its equivalent) may be most susceptible, particularly when their systemic corticosteroids have been almost completely withdrawn. During this period of HPA suppression, patients may exhibit signs and symptoms of adrenal insufficiency when exposed to trauma, surgery, or infection (particularly gastroenteritis) or other conditions associated with severe electrolyte loss. Although TRELEGY may control COPD or asthma symptoms during these episodes, in recommended doses it supplies less than normal physiological amounts of glucocorticoid systemically and does NOT provide the mineralocorticoid activity that is necessary for coping with these emergencies.

During periods of stress, a severe COPD exacerbation, or a severe asthma attack, patients who have been withdrawn from systemic corticosteroids should be instructed to resume oral corticosteroids (in large doses) immediately and to contact their health care practitioner for further instruction. These patients should also be instructed to carry a warning card indicating that they may need supplementary systemic corticosteroids during periods of stress, a severe COPD exacerbation, or a severe asthma attack.

Patients requiring oral corticosteroids should be weaned slowly from systemic corticosteroid use after transferring to TRELEGY. Prednisone reduction can be accomplished by reducing the daily prednisone dose by 2.5 mg on a weekly basis during therapy with TRELEGY. Lung function (FEV_1), beta-agonist use, and COPD or asthma symptoms should be carefully monitored during withdrawal of oral corticosteroids. In addition, patients should be observed for signs and symptoms of adrenal insufficiency, such as fatigue, lassitude, weakness, nausea and vomiting, and hypotension.

Unmasking of Allergic Conditions Previously Suppressed by Systemic Corticosteroids

Transfer of patients from systemic corticosteroid therapy to TRELEGY may unmask allergic conditions previously suppressed by the systemic corticosteroid therapy (eg, rhinitis, conjunctivitis, eczema, arthritis, eosinophilic conditions).

Corticosteroid Withdrawal Symptoms

During withdrawal from oral corticosteroids, some patients may experience symptoms of systemically active corticosteroid withdrawal (eg, joint and/or muscular pain, lassitude, depression) despite maintenance or even improvement of respiratory function.

5.8 Hypercorticism and Adrenal Suppression

Inhaled fluticasone furoate is absorbed into the circulation and can be systemically active. Effects of fluticasone furoate on the HPA axis are not observed with the therapeutic doses of fluticasone furoate in TRELEGY. However, exceeding the recommended dosage or coadministration with a strong cytochrome P450 3A4 (CYP3A4) inhibitor may result in HPA dysfunction *[see Warnings and Precautions (5.9), Drug Interactions (7.1)]*.

Because of the possibility of significant systemic absorption of ICS in sensitive patients, patients treated with TRELEGY should be observed carefully for any evidence of systemic corticosteroid effects. Particular care should be taken in observing patients postoperatively or during periods of stress for evidence of inadequate adrenal response.

It is possible that systemic corticosteroid effects such as hypercorticism and adrenal suppression (including adrenal crisis) may appear in a small number of patients who are sensitive to these effects. If such effects occur, reduce the dose of TRELEGY slowly, consistent with accepted procedures for reducing systemic corticosteroids, and consider other treatments for management of COPD or asthma symptoms.

5.9 Drug Interactions With Strong Cytochrome P450 3A4 Inhibitors

Caution should be exercised when considering the coadministration of TRELEGY with ketoconazole and other known strong CYP3A4 inhibitors (including, but not limited to, ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleandomycin, voriconazole) because increased systemic corticosteroid and increased cardiovascular adverse effects may occur *[see Drug Interactions (7.1), Clinical Pharmacology (12.3) of full prescribing information]*.

5.10 Paradoxical Bronchospasm

As with other inhaled therapies, TRELEGY can produce paradoxical bronchospasm, which may be life threatening. If paradoxical bronchospasm occurs following dosing with TRELEGY, it should be treated immediately with an inhaled, short-acting bronchodilator; TRELEGY should be discontinued immediately; and alternative therapy should be instituted.

5.11 Hypersensitivity Reactions, Including Anaphylaxis

Hypersensitivity reactions such as anaphylaxis, angioedema, rash, and urticaria may occur after administration of TRELEGY. Discontinue TRELEGY if such reactions occur. There have been reports of anaphylactic reactions in patients with severe milk protein allergy after inhalation of other powder medications containing lactose; therefore, patients with severe milk protein allergy should not use TRELEGY *[see Contraindications (4)]*.

Continued on next page

5.12 Cardiovascular Effects

Vilanterol, like other beta$_2$-agonists, can produce a clinically significant cardiovascular effect in some patients as measured by increases in pulse rate, systolic or diastolic blood pressure, and also cardiac arrhythmias, such as supraventricular tachycardia and extrasystoles. If such effects occur, TRELEGY may need to be discontinued. In addition, beta-agonists have been reported to produce electrocardiographic changes, such as flattening of the T wave, prolongation of the QTc interval, and ST segment depression, although the clinical significance of these findings is unknown *[see Clinical Pharmacology (12.2) of full prescribing information]*. Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs.

TRELEGY, like other sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

In a 52-week trial of subjects with COPD, the exposure-adjusted rates for any on-treatment major adverse cardiac event, including non-fatal central nervous system hemorrhages and cerebrovascular conditions, non-fatal myocardial infarction (MI), non-fatal acute MI, and adjudicated on-treatment death due to cardiovascular events, was 2.2 per 100 patient-years for TRELEGY (n = 4,151), 1.9 per 100 patient-years for fluticasone furoate/vilanterol 100/25 mcg (n = 4,134), and 2.2 per 100 patient-years for umeclidinium/vilanterol 62.5/25 mcg (n = 2,070). Adjudicated on-treatment deaths due to cardiovascular events occurred in 20 of 4,151 patients (0.54 per 100 patient-years) receiving TRELEGY; 27 of 4,134 patients (0.78 per 100 patient-years) receiving fluticasone furoate/vilanterol; and 16 of 2,070 patients (0.94 per 100 patient-years) receiving umeclidinium/vilanterol.

In a mortality trial with fluticasone furoate/vilanterol with a median treatment duration of 1.5 years in 16,568 subjects with moderate COPD and cardiovascular disease, the annualized incidence rate of adjudicated cardiovascular events (composite of myocardial infarction, stroke, unstable angina, transient ischemic attack, or on-treatment death due to cardiovascular events) was 2.5 per 100 patient-years for fluticasone furoate/vilanterol 100/25 mcg, 2.7 for placebo, 2.4 for fluticasone furoate 100 mcg, and 2.6 for vilanterol 25 mcg. Adjudicated, on-treatment deaths due to cardiovascular events occurred in 82 subjects receiving fluticasone furoate/vilanterol 100/25 mcg, 86 subjects receiving placebo, 80 subjects receiving fluticasone furoate 100 mcg, and 90 subjects receiving vilanterol 25 mcg (annualized incidence rate ranged from 1.2 to 1.3 per 100 patient-years for the treatment groups).

5.13 Reduction in Bone Mineral Density

Decreases in bone mineral density (BMD) have been observed with long-term administration of products containing ICS. The clinical significance of small changes in BMD with regard to long-term consequences such as fracture is unknown. Patients with major risk factors for decreased bone mineral content, such as prolonged immobilization, family history of osteoporosis, postmenopausal status, tobacco use, advanced age, poor nutrition, or chronic use of drugs that can reduce bone mass (eg, anticonvulsants, oral corticosteroids) should be monitored and treated with established standards of care. Since patients with COPD often have multiple risk factors for reduced BMD, assessment of BMD is recommended prior to initiating TRELEGY and periodically thereafter. If significant reductions in BMD are seen and TRELEGY is still considered medically important for that patient's COPD therapy, use of therapy to treat or prevent osteoporosis should be strongly considered.

5.14 Glaucoma and Cataracts, Worsening of Narrow-Angle Glaucoma

Glaucoma, increased intraocular pressure, and cataracts have been reported in patients with COPD or asthma following the long-term administration of ICS or with use of inhaled anticholinergics. TRELEGY should be used with caution in patients with narrow-angle glaucoma. Prescribers and patients should also be alert for signs and symptoms of acute narrow-angle glaucoma (eg, eye pain or discomfort, blurred vision, visual halos, or colored images in association with red eyes from conjunctival congestion and corneal edema). Instruct patients to consult a healthcare provider immediately if any of these signs or symptoms develop. Consider referral to an ophthalmologist in patients who develop ocular symptoms or use TRELEGY long term.

5.15 Worsening of Urinary Retention

TRELEGY, like all medicines containing an anticholinergic, should be used with caution in patients with urinary retention. Prescribers and patients should be alert for signs and symptoms of urinary retention (eg, difficulty passing urine, painful urination), especially in patients with prostatic hyperplasia or bladder-neck obstruction. Instruct patients to consult a healthcare provider immediately if any of these signs or symptoms develop.

5.16 Coexisting Conditions

TRELEGY, like all therapies containing sympathomimetic amines, should be used with caution in patients with convulsive disorders or thyrotoxicosis and in those who are unusually responsive to sympathomimetic amines. Doses of the related beta$_2$-adrenoceptor agonist albuterol, when administered intravenously, have been reported to aggravate preexisting diabetes mellitus and ketoacidosis.

5.17 Hypokalemia and Hyperglycemia

Beta-adrenergic agonist medicines may produce significant hypokalemia in some patients, possibly through intracellular shunting, which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation. Beta-agonist medications may produce transient hyperglycemia in some patients.

5.18 Effect on Growth

Orally inhaled corticosteroids may cause a reduction in growth velocity when administered to children and adolescents. *[See Use in Specific Populations (8.4).]*

6 ADVERSE REACTIONS

The following adverse reactions are described in greater detail in other sections:

- Serious asthma-related events – hospitalizations, intubations, death *[see Warnings and Precautions (5.1)]*
- *Candida albicans* infection *[see Warnings and Precautions (5.4)]*
- Increased risk of pneumonia in COPD *[see Warnings and Precautions (5.5)]*
- Immunosuppression and risk of infections *[see Warnings and Precautions (5.6)]*
- Hypercorticism and adrenal suppression *[see Warnings and Precautions (5.8)]*
- Paradoxical bronchospasm *[see Warnings and Precautions (5.10)]*
- Cardiovascular effects *[see Warnings and Precautions (5.12)]*
- Reduction in bone mineral density *[see Warnings and Precautions (5.13)]*
- Worsening of narrow-angle glaucoma *[see Warnings and Precautions (5.14)]*
- Worsening of urinary retention *[see Warnings and Precautions (5.15)]*

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

6.1 Clinical Trials Experience in Chronic Obstructive Pulmonary Disease

The safety of TRELEGY in COPD is based on the safety data from two 12-week treatment trials with the coadministration of umeclidinium and the fixed-dose combination of fluticasone furoate/vilanterol and a 52-week long-term trial of TRELEGY 100/62.5/25 mcg compared with the fixed-dose combinations of fluticasone furoate/vilanterol and umeclidinium/vilanterol *[see Clinical Studies (14.1) of full prescribing information]*.

Trials 1 and 2

Two 12-week treatment trials (Trial 1, NCT #01957163 and Trial 2, NCT #02119286) evaluated the coadministration of umeclidinium + fluticasone furoate/vilanterol, the components of TRELEGY, compared with placebo +

Table 2. Adverse Reactions With Umeclidinium + Fluticasone Furoate/ Vilanterol With ≥1% Incidence and More Common Than Placebo + Fluticasone Furoate/Vilanterol in Subjects with COPD (Trials 1 and 2)

Adverse Reaction	Umec + FF/VI (n=412) %	Placebo + FF/VI (n=412) %
Nervous system disorders		
Headache	4	3
Dysgeusia	2	<1
Musculoskeletal and connective tissue disorders		
Back pain	4	2
Respiratory, thoracic, and mediastinal disorders		
Cough	1	<1
Oropharyngeal pain	1	0
Gastrointestinal disorders		
Diarrhea	2	<1
Infections and infestations		
Gastroenteritis	1	0

Umec = Umeclidinium, FF/VI = Fluticasone Furoate/Vilanterol.

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TRELEGY ELLIPTA (fluticasone furoate, umeclidinium, and vilanterol inhalation powder), for oral inhalation *(cont'd)*

fluticasone furoate/vilanterol. A total of 824 subjects with COPD across two 12-week, randomized, double-blind clinical trials received at least 1 dose of umeclidinium 62.5 mcg + fluticasone furoate/vilanterol 100/25 mcg or placebo + fluticasone furoate/vilanterol 100/25 mcg administered once daily (mean age: 64 years; 92% White, 66% male across all treatments) *[see Clinical Studies (14.1) of full prescribing information]*. The incidence of adverse reactions associated with the use of umeclidinium 62.5 mcg + fluticasone furoate/vilanterol 100/25 mcg presented in Table 2 (on preceding page) is based on the two 12-week trials.

Trial 3 - Long-term Safety Data

A 52-week trial (Trial 3, NCT #02164513) evaluated the long-term safety of TRELEGY 100/62.5/25 mcg compared with the fixed-dose combinations of fluticasone furoate/vilanterol 100/25 mcg and umeclidinium/vilanterol 62.5/25 mcg. A total of 10,355 subjects with COPD with a history of moderate or severe exacerbations within the prior 12 months were randomized (2:2:1) to receive TRELEGY 100/62.5/25 mcg, fluticasone furoate/vilanterol, or umeclidinium/vilanterol administered once daily in a double-blind clinical trial (mean age: 65 years, 77% White, 66% male across all treatments) *[see Clinical Studies (14.1) of full prescribing information]*.

The incidence of adverse reactions in the long-term trial were consistent with those in Trials 1 and 2. However, in addition to the adverse reactions shown in Table 2, adverse reactions occurring in ≥1% of the subjects treated with TRELEGY 100/62.5/25 mcg (n = 4,151) for up to 52 weeks also included upper respiratory tract infection, pneumonia *[see Warnings and Precautions (5.5)]*, bronchitis, oral candidiasis *[see Warnings and Precautions (5.4)]*, arthralgia, influenza, sinusitis, pharyngitis, rhinitis, constipation, urinary tract infection, and dysphonia.

6.2 Clinical Trials Experience in Asthma

The safety of TRELEGY in asthma is based on a randomized, double-blind, parallel-group, active-controlled trial of 24 to 52 weeks' duration (Trial 4, NCT #02924688) that enrolled 2,436 adult subjects inadequately controlled on their current treatment of combination therapy (ICS plus a LABA) *[see Clinical Studies (14.2) of full prescribing information]*. In the overall population, 62% were female and 80% were White; mean age was 53 years. The incidence of adverse reactions occurring in ≥1% of the subjects treated with TRELEGY 100/62.5/25 mcg or TRELEGY 200/62.5/25 mcg is shown in Table 3 below. Adverse reactions observed for the groups treated with TRELEGY were similar to those observed for the fluticasone furoate/vilanterol arms.

6.3 Postmarketing Experience

In addition to adverse reactions reported from clinical trials, the following adverse reactions have been identified during postapproval use of TRELEGY. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These events have been chosen for inclusion due to either their seriousness, frequency of reporting, or causal connection to TRELEGY or a combination of these factors.

Immune System Disorders

Hypersensitivity reactions, including anaphylaxis, angioedema, rash, and urticaria.

7 DRUG INTERACTIONS

7.1 Inhibitors of Cytochrome P450 3A4

Fluticasone furoate and vilanterol are substrates of CYP3A4. Concomitant administration of the strong CYP3A4 inhibitor ketoconazole increases the systemic exposure to fluticasone furoate and vilanterol. Caution should be exercised when considering the coadministration of TRELEGY with ketoconazole and other known strong CYP3A4 inhibitors *[see Warnings and Precautions (5.9), Clinical Pharmacology (12.3) of full prescribing information]*.

7.2 Monoamine Oxidase Inhibitors, Tricyclic Antidepressants, and QTc Prolonging Drugs

Vilanterol, like other beta$_2$-agonists, should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval or within 2 weeks of discontinuation of such agents, because the effect of adrenergic agonists on the cardiovascular system may be potentiated by these agents. Drugs that are known to prolong the QTc interval have an increased risk of ventricular arrhythmias.

7.3 Beta-adrenergic Receptor Blocking Agents

Beta-blockers not only block the pulmonary effect of beta-agonists, such as vilanterol, but may also produce severe bronchospasm in patients with COPD or asthma. Therefore, patients with COPD or asthma should not normally be treated with beta-blockers. However, under certain circumstances, there may be no acceptable alternatives to the use of beta-adrenergic blocking agents for these patients; cardioselective beta-blockers could be considered, although they should be administered with caution.

7.4 Non–Potassium-Sparing Diuretics

The electrocardiographic changes and/or hypokalemia that may result from the administration of non–potassium-sparing diuretics (such as loop or thiazide diuretics) can be acutely worsened by beta-agonists, especially

Table 3. Adverse Reactions With TRELEGY With ≥1% Incidence in Subjects With Asthma (Trial 4)

Adverse Reaction	TRELEGY 200/62.5/25 mcg (n = 408) %	TRELEGY 100/62.5/25 mcg (n =406) %	FF/VI 200/25 mcg (n = 406) %	FF/VI 100/25 mcg (n = 407) %
Infections and infestations				
Pharyngitis/nasopharyngitis	15	17	16	16
Upper respiratory tract infection/viral upper respiratory tract infection	7	5	6	7
Bronchitis	5	4	5	3
Respiratory tract infection/viral respiratory tract infection	3	4	2	4
Sinusitis/acute sinusitis	3	2	2	3
Urinary tract infection	2	<1	<1	1
Rhinitis	1	2	2	3
Influenza	1	4	2	3
Pneumonia	<1	1	2	2
Nervous system disorders				
Headache	5	9	6	7
Musculoskeletal and connective tissue disorders				
Back pain	2	3	1	4
Respiratory, thoracic, and mediastinal disorders				
Dysphonia	1	1	2	1
Oropharyngeal pain	1	1	<1	<1
Cough	1	<1	1	1

FF/VI = Fluticasone Furoate/Vilanterol.

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when the recommended dose of the beta-agonist is exceeded. Although the clinical significance of these effects is not known, caution is advised in the coadministration of beta-agonists with non–potassium-sparing diuretics.

7.5 Anticholinergics

There is potential for an additive interaction with concomitantly used anticholinergic medicines. Therefore, avoid coadministration of TRELEGY with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic adverse effects *[see Warnings and Precautions (5.14, 5.15)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are insufficient data on the use of TRELEGY or its individual components, fluticasone furoate, umeclidinium, and vilanterol, in pregnant women to inform a drug-associated risk.

Clinical Considerations

Disease-Associated Maternal and/or Embryofetal Risk: In women with poorly or moderately controlled asthma, there is an increased risk of several perinatal outcomes such as pre-eclampsia in the mother and prematurity, low birth weight, and small for gestational age in the neonate. Pregnant women should be closely monitored and medication adjusted as necessary to maintain optimal control of asthma.

Labor or Delivery: TRELEGY should be used during late gestation and labor only if the potential benefit justifies the potential for risks related to beta-agonists interfering with uterine contractility.

8.2 Lactation

Risk Summary

There is no information available on the presence of fluticasone furoate, umeclidinium, or vilanterol in human milk; the effects on the breastfed child; or the effects on milk production. Umeclidinium was detected in the plasma of offspring of lactating rats treated with umeclidinium, suggesting its presence in maternal milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for TRELEGY and any potential adverse effects on the breastfed child from fluticasone furoate, umeclidinium, or vilanterol or from the underlying maternal condition.

8.4 Pediatric Use

TRELEGY is not indicated for use in children and adolescents. The safety and efficacy in pediatric patients (aged 17 years and younger) have not been established.

Effects on Growth

Orally inhaled corticosteroids may cause a reduction in growth velocity when administered to children and adolescents.

Controlled clinical trials have shown that ICS may cause a reduction in growth in children. In these trials, the mean reduction in growth velocity was approximately 1 cm/year (range: 0.3 to 1.8 cm/year) and appears to be related to dose and duration of exposure. This effect has been observed in the absence of laboratory evidence of HPA axis suppression, suggesting that growth velocity is a more sensitive indicator of systemic corticosteroid exposure in children than some commonly used tests of HPA axis function. The long-term effects of this reduction in growth velocity associated with orally inhaled corticosteroids, including the impact on final adult height, are unknown.

A randomized, double-blind, parallel-group, multicenter, 1-year, placebo-controlled trial evaluated the effect of once-daily treatment with 110 mcg of fluticasone furoate in the nasal spray formulation on growth velocity assessed by stadiometry. The subjects were 474 prepubescent children (girls aged 5 to 7.5 years and boys aged 5 to 8.5 years). Mean growth velocity over the 52-week treatment period was lower in the subjects receiving fluticasone furoate nasal spray (5.19 cm/year) compared with placebo (5.46 cm/year). The mean reduction in growth velocity was 0.27 cm/year (95% CI: 0.06, 0.48) *[see Warnings and Precautions (5.18)]*.

8.5 Geriatric Use

Based on available data, no adjustment of the dosage of TRELEGY in geriatric patients is necessary, but greater sensitivity in some older individuals cannot be ruled out.

In COPD Trials 1 and 2 (coadministration trials), 189 subjects aged 65 years and older, of which 39 subjects were aged 75 years and older, were administered umeclidinium 62.5 mcg + fluticasone furoate/vilanterol 100/25 mcg. In COPD Trial 3, 2,265 subjects aged 65 years and older, of which 565 subjects were aged 75 years and older, were administered TRELEGY. In an asthma clinical trial (Trial 4), 159 subjects aged 65 years and older, of which 27 subjects were aged 75 years and older, were administered TRELEGY 100/62.5/25 mcg or TRELEGY 200/62.5/25 mcg. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger subjects.

8.6 Hepatic Impairment

TRELEGY has not been studied in subjects with hepatic impairment. Information on the individual components is provided below.

Fluticasone Furoate/Vilanterol

Fluticasone furoate systemic exposure increased by up to 3-fold in subjects with hepatic impairment compared with healthy subjects. Hepatic impairment had no effect on vilanterol systemic exposure. Use TRELEGY with caution in patients with moderate or severe hepatic impairment. Monitor patients for corticosteroid-related side effects *[see Clinical Pharmacology (12.3) of full prescribing information]*.

Umeclidinium

Patients with moderate hepatic impairment (Child-Pugh score of 7-9) showed no relevant increases in C_{max} or AUC, nor did protein binding differ between subjects with moderate hepatic impairment and their healthy controls. Studies in subjects with severe hepatic impairment have not been performed *[see Clinical Pharmacology (12.3) of full prescribing information]*.

8.7 Renal Impairment

TRELEGY has not been studied in subjects with renal impairment. Information on the individual components is provided below.

Fluticasone Furoate/Vilanterol

There were no significant increases in either fluticasone furoate or vilanterol exposure in subjects with severe renal impairment (CrCl <30 mL/min) compared with healthy subjects. No dosage adjustment is required in patients with renal impairment *[see Clinical Pharmacology (12.3) of full prescribing information]*.

Umeclidinium

Patients with severe renal impairment (CrCl <30 mL/min) showed no relevant increases in C_{max} or AUC, nor did protein binding differ between subjects with severe renal impairment and their healthy controls. No dosage adjustment is required in patients with renal impairment *[see Clinical Pharmacology (12.3) of full prescribing information]*.

10 OVERDOSAGE

No human overdosage data has been reported for TRELEGY.

TRELEGY contains fluticasone furoate, umeclidinium, and vilanterol; therefore, the risks associated with overdosage for the individual components described below apply to TRELEGY. Treatment of overdosage consists of discontinuation of TRELEGY together with institution of appropriate symptomatic and/or supportive therapy. The judicious use of a cardioselective beta-receptor blocker may be considered, bearing in mind that such medicine can produce bronchospasm. Cardiac monitoring is recommended in cases of overdosage.

10.1 Fluticasone Furoate

Because of low systemic bioavailability (15.2%) and an absence of acute drug-related systemic findings in clinical trials, overdosage of fluticasone furoate is unlikely to require any treatment other than observation. If used at excessive doses for prolonged periods, systemic effects such as hypercorticism may occur *[see Warnings and Precautions (5.8)]*.

10.2 Umeclidinium

High doses of umeclidinium may lead to anticholinergic signs and symptoms.

10.3 Vilanterol

The expected signs and symptoms with overdosage of vilanterol are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the signs and symptoms of beta-adrenergic stimulation (eg, seizures, angina, hypertension or hypotension, tachycardia with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, muscle cramps, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, insomnia, hyperglycemia, hypokalemia, metabolic acidosis). As with all inhaled sympathomimetic medicines, cardiac arrest and even death may be associated with an overdose of vilanterol.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Serious Asthma-Related Events

Inform patients with asthma that LABA when used alone increases the risk of asthma-related hospitalization or asthma-related death. Available data show

Continued on next page

that when ICS and LABA are used together, such as with TRELEGY, there is not a significant increase in the risk of these events. *[See Warnings and Precautions (5.1).]*

Not for Acute Symptoms

Inform patients that TRELEGY is not meant to relieve acute symptoms of COPD or asthma and extra doses should not be used for that purpose. Advise patients to treat acute symptoms with an inhaled, short-acting $beta_2$-agonist such as albuterol. Provide patients with such medication and instruct them in how it should be used.

Instruct patients to seek medical attention immediately if they experience any of the following:

- Decreasing effectiveness of inhaled, short-acting $beta_2$-agonists
- Need for more inhalations than usual of inhaled, short-acting $beta_2$-agonists
- Significant decrease in lung function as outlined by the physician

Tell patients they should not stop therapy with TRELEGY without physician/provider guidance since symptoms may recur after discontinuation. *[See Warnings and Precautions (5.2).]*

Do Not Use Additional Long-acting $Beta_2$-agonists

Instruct patients not to use other LABA for COPD and asthma. *[See Warnings and Precautions (5.3).]*

Oropharyngeal Candidiasis

Inform patients that localized infections with *Candida albicans* occurred in the mouth and pharynx in some patients. If oropharyngeal candidiasis develops, treat it with appropriate local or systemic (ie, oral) antifungal therapy while still continuing therapy with TRELEGY, but at times therapy with TRELEGY may need to be temporarily interrupted under close medical supervision. Advise patients to rinse the mouth with water without swallowing after inhalation to help reduce the risk of thrush. *[See Warnings and Precautions (5.4).]*

Pneumonia

Patients with COPD have a higher risk of pneumonia; instruct them to contact their healthcare providers if they develop symptoms of pneumonia. *[See Warnings and Precautions (5.5).]*

Immunosuppression and Risk of Infections

Warn patients who are on immunosuppressant doses of corticosteroids to avoid exposure to chickenpox or measles and, if exposed, to consult their physicians without delay. Inform patients of potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex. *[See Warnings and Precautions (5.6).]*

Hypercorticism and Adrenal Suppression

Advise patients that TRELEGY may cause systemic corticosteroid effects of hypercorticism and adrenal suppression. Additionally, inform patients that deaths due to adrenal insufficiency have occurred during and after transfer from systemic corticosteroids. Patients should taper slowly from systemic corticosteroids if transferring to TRELEGY. *[See Warnings and Precautions (5.8).]*

Paradoxical Bronchospasm

As with other inhaled medicines, TRELEGY can cause paradoxical bronchospasm. If paradoxical bronchospasm occurs, instruct patients to discontinue TRELEGY and contact their healthcare provider right away. *[See Warnings and Precautions (5.10).]*

Hypersensitivity Reactions, including Anaphylaxis

Advise patients that hypersensitivity reactions (eg, anaphylaxis, angioedema, rash, urticaria) may occur after administration of TRELEGY. Instruct patients to discontinue TRELEGY if such reactions occur. There have been reports of anaphylactic reactions in patients with severe milk protein allergy after inhalation of other powder medications containing lactose; therefore, patients with severe milk protein allergy should not use TRELEGY. *[See Warnings and Precautions (5.11).]*

Reduction in Bone Mineral Density

Advise patients who are at an increased risk for decreased BMD that the use of corticosteroids may pose an additional risk. *[See Warnings and Precautions (5.13).]*

Glaucoma and Cataracts

Advise patients that long-term use of ICS may increase the risk of some eye problems (cataracts or glaucoma); consider regular eye examinations.

Instruct patients to be alert for signs and symptoms of acute narrow-angle glaucoma (eg, eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema). Instruct patients to consult a physician immediately if any of these signs or symptoms develop. *[See Warnings and Precautions (5.14).]*

Worsening of Urinary Retention

Instruct patients to be alert for signs and symptoms of urinary retention (eg, difficulty passing urine, painful urination). Instruct patients to consult a physician immediately if any of these signs or symptoms develop. *[See Warnings and Precautions (5.15).]*

Risks Associated with Beta-agonist Therapy

Inform patients of adverse effects associated with $beta_2$-agonists, such as palpitations, chest pain, rapid heart rate, tremor, or nervousness. Instruct patients to consult a health care practitioner immediately should any of these signs and symptoms develop. *[See Warnings and Precautions (5.12).]*

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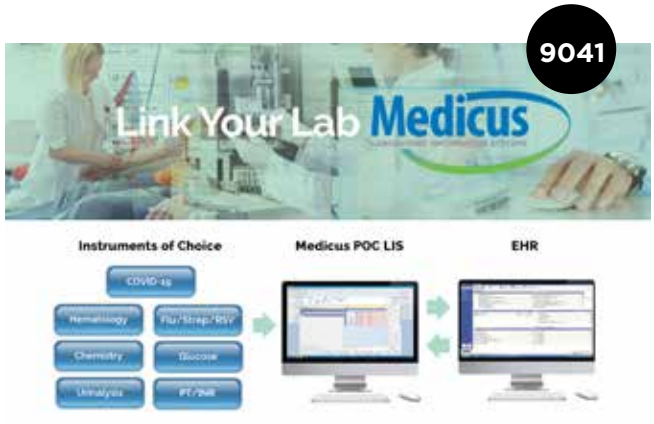
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A CRASH COURSE IN MEDICAL SOCIAL MEDIA



BY DYLAN CHADWICK

I recently discovered one of the internet's greatest contribution's to pop-culture obsessives: the Reddit AMA. In Medical parlance, "AMA" stands for "American Medical Association" but on the internet, it's short for "ask me anything." Call me uncultured, late to the game, or uninformed (actually, don't), but the internet's premiere discussion board took a few more years than normal to get its hooks in me.

What I liked, of course, was the unfettered access I got to a niche celebrity, in this case a Simpsons writer. Reddit users could ask specific questions, which said celebrity could answer at their own discretion. Protected in the cloak of anonymity, users could even ask embarrassing ones, without feeling too much stigma, and anyone casually browsing the site was treated to a bevy of information, an entire conversation they could read at their own leisure. Of course, one of Reddit's more prescient contributions to the internet community however, is it's "upvoting and downvoting" feature. This allows users to help "boost" particular comments or pieces of discussion they find particularly valuable, and to downvote ones they deem as irrelevant. It's a "checks and balances" system which ensures that the most meaningful data stands out and that which doesn't help gets buried. Many feel uneasy turning over such a large portion of internet discussion to faceless users, but I'm wont to think that in any capacity, the "cream" will rise.

We've seen physicians engaging social media with more and more regularity over the last five years. Where once this kind of stake in internet real estate seemed novel, an internet presence is now a practical a requirement for any small-medium sized business owner. For every disadvantage a particular social media platform may possess, many of them also carry a substantial amount of utility for a physician. Here's a quick and dirty guide to social media platforms and how they'll relate to a physician.

Instagram

With over 1 billion users, most are familiar with the catchy photography app. Instagram allows users to engage with their community via photographs, and a bevy of fun filters to lend their photos a stylistic edge. Granted, the physician application here is minimal, but occupational Instagrams aren't unheard of anymore. Many enjoy the "backstage" feel that a company Instragram account can lend them, showing users the "behind the scenes" happenings of their particular organization,. Perhaps this is why hip shared co-working spaces in SoHo and London tend to have such huge follower-bases.

I'm not recommending that physicians go about posting their trophy surgeries on Instagram (surely there's some HIPPA red tape there) but for anyone trying to cultivate a buzz, or "new age" interest around their practice or facility, may look deeper into the benefits of a company instagram account. These can showcase innocuous details of the practice like waiting room conditions, decor and even new equipment. I've even seen Dentists and orthodontists using them to show off newly "crowned" patients. With a little discretion, a company Instragram account can be the ultimate low-stakes social media platform to get a practice some web presence.

Twitter

Twitter has become one of the web's leading communities for sharing content and ideas, through a unique "bulletin board" of 280 character limit "tweets." While some find these kinds of character restrictions limiting, others appreciate the quick and breezy way in which they can fire off



an idea or a question to their online community, and with which others can respond.

Many physicians and medical authorities have taken to Twitter also because it's a way to share links and other existing media, and to connect and share information in a low key manner. Obviously, because of Twitter's specific aesthetic restrictions, one cannot share gobs and gobs of information, but for a physician with access to internet resources and helpful articles, it can be a good way to direct patients to quality information online, without having to go through too much personalization of investment.

Facebook

Facebook is likely the leading social media platform in the world as the it's got about twice as many users as the entire country of China (2.8 Billion) using it monthly. We've no doubt heard stories of physicians getting themselves into trouble on Facebook by connecting with patients outside of those confines. The trick is that Facebook works on both a personal level and a business level.

Physicians who want an easy place to direct patients online, somewhere they can post links or a personal portal to their practice (with address, wait times, etc.) can set up a business profile for their patients. Those who wish to have a personal profile can use one for more personal information which they can be more selective with. Setting up profiles on these accounts is quick and easy, even if a physician doesn't wish to maintain these profiles, they can still help them with SEO. When anyone types a physician's name into Google, savvy physicians can ensure it's their personal sites that come up.

Reddit

As mentioned earlier, Reddit can add to the medical community, or virtually any other special interest community on the internet. It's divided up into a series of "subreddits" which are essentially categories for the message board. This allows physicians to find boards that relate specifically to medicine, and other related topics.

Gregarious physicians can pose questions to the community, or simply engage with other users. Of course, HIPPA compliance is always a factor, but many find that when they can just be an internet user, they can ask questions more freely that they'd otherwise be too embarrassed to ask in a formal setting.

A Personal Blog

Personal blogs are only for the die hards as they'll have to coordinate their own content. The Good thing is, in today's internet client, many blog authors are willing to contribute to others platforms and such, creating a literal web of physician curated content that's as goods a resource for patients and physicians alike. One of the best examples of how these blogs can work is KevinMD.com, a site which hosts content from physicians and patients and covers everything from open editorials to hard physician news.

In today's climate where social media platforms drive much of our internet traffic and opinions, there's simply no excuse for any physician to be completely without them in this day and age.



IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Few cases (0.36%) of adverse reactions of cystitis, pyelonephritis and other upper urinary tract infection (UTI) have been reported in Phexxi® clinical studies. Of these, one case of pyelonephritis was considered serious and required hospitalization. Avoid use of Phexxi® in females of reproductive potential with a history of recurrent urinary tract infection or urinary tract abnormalities.

ADVERSE REACTIONS

Most common adverse reactions were vulvovaginal burning sensation, vulvovaginal pruritus, vulvovaginal mycotic infection, urinary tract infection, vulvovaginal discomfort, bacterial vaginosis, vaginal discharge, genital discomfort, dysuria, and vulvovaginal pain. 9.8% of male partners reported local discomfort.

Patients should be counseled on the following:

- **To contact and consult with their healthcare provider for severe or prolonged genital irritation or if experiencing urinary tract symptoms.**
- **To discontinue Phexxi® if they develop a local hypersensitivity reaction.**
- **That Phexxi® does not protect against HIV infection or other sexually transmitted infections.**
- **To avoid Phexxi® use with vaginal rings.**

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For the women in your practice who...

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- Currently use condoms or withdrawal method
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How to prescribe Phexxi®

PHEXXI® VAGINAL GEL (5 g per applicator)

Sig: Administer 1 applicator intravaginally immediately **before** or up to 1 hour before EACH act of vaginal intercourse as needed.

Rx

Dispense: # 12 applicators

NDC: 69751-100-12

Refill: 11

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To report SUSPECTED ADVERSE REACTIONS, contact Evofem at toll-free phone 1-833-EVFMBIO or you may contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

INDICATIONS AND USAGE

Phexxi® (lactic acid, citric acid, and potassium bitartrate) vaginal gel 1.8%, 1%, 0.4% is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.

LIMITATIONS OF USE

Phexxi® is not effective for the prevention of pregnancy when administered after intercourse.

Please see full Prescribing Information for Phexxi®.
Please see Brief Summary on the following page.

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phexxi®

(lactic acid, citric acid, and potassium bitartrate) Vaginal Gel 1.8%, 1%, 0.4%

BRIEF SUMMARY: Consult the Package Insert for complete Prescribing Information

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PHEXXI is not effective for the prevention of pregnancy when administered after intercourse.

WARNINGS AND PRECAUTIONS

Cystitis and Pyelonephritis

Among 2804 subjects who received PHEXXI in Studies 1 and 2, 0.36% (n=10) reported adverse reactions of cystitis, pyelonephritis, or other upper urinary tract infection (UTI). Of these, one case of pyelonephritis was considered serious and required hospitalization. Avoid use of PHEXXI in females of reproductive potential with a history of recurrent urinary tract infection or urinary tract abnormalities.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of PHEXXI (pre-filled applicator with 5-gram dose) has been evaluated in two clinical trials (Study 1 and Study 2) in 2804 subjects (over 19,000 cycles of exposure). The racial/ethnic distribution was 66% White, 27% Black or African American, 2% Asian, 1% American Indian or Alaska Native, 0.3% Native Hawaiian or Pacific Islander, and 5% other; 32% of the study population was Hispanic. Study 1 included a one-year extension phase where 342 U.S. subjects were exposed to PHEXXI for 13 cycles.

Hypersensitivity Reaction:

Of the 2804 PHEXXI-treated subjects in Studies 1 and 2, one subject reported a suspected drug hypersensitivity. Avoid PHEXXI use in females of reproductive potential with suspected hypersensitivity to the ingredients in PHEXXI.

The most common adverse reactions (≥10%) in the U.S. population in Studies 1 and 2 (n = 2480) were: vulvovaginal burning sensation (18.0%) and vulvovaginal pruritus (14.5%). The majority of these adverse reactions were mild and few led to discontinuation. Table 1 summarizes the most common adverse reactions (≥ 2%) reported by subjects using PHEXXI in the U.S.

Table 1. Adverse Reactions that Occurred in ≥ 2% of Subjects Who Used PHEXXI to Prevent Pregnancy (Studies 1 and 2 – U.S. population only)

Adverse Reaction	PHEXXI (N=2480) (%)
Vulvovaginal Burning Sensation	18.0
Vulvovaginal Pruritus	14.5
Vulvovaginal Mycotic Infection*	9.1
Urinary Tract Infection†,‡	9.0
Vulvovaginal Discomfort	9.0
Bacterial Vaginosis	8.4
Vaginal Discharge	5.5
Genital Discomfort	4.1
Dysuria	3.1
Vulvovaginal pain	2.1

*Includes preferred terms (PT) vulvovaginal mycotic infection and vulvovaginal candidiasis.
†Includes PTs urinary tract infection, streptococcal urinary tract infection, Escherichia urinary tract infection, and urinary tract infection bacterial.
‡Does not include PTs cystitis, kidney infection, and pyelonephritis [see *Warnings and Precautions (5.1) of PHEXXI Full Prescribing Information*].

Among subjects who used PHEXXI in Studies 1 and 2, 1.6% discontinued from the clinical trials due to an adverse reaction. The most common adverse reactions leading to study discontinuation were vulvovaginal burning sensation (0.7%); and vulvovaginal pruritus and vulvovaginal discomfort (0.1% each).

Adverse Reactions in Male Partners:

Among male partners of subjects who used PHEXXI for contraception in Study 2, 9.8% (131 of 1330) reported symptoms of local discomfort (burning, itching, pain, and "other"). Of these local discomfort symptoms, 74.7% were mild, 21.4% were moderate, and 3.9% were severe. Two subjects discontinued participation in the study due to male partner symptoms.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There is no use for PHEXXI in pregnancy; therefore, discontinue PHEXXI during pregnancy. There are no data with the use of PHEXXI in pregnant women or animals. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4 percent and 15 to 20 percent, respectively.

Lactation

Risk Summary

There are no data on the presence of lactic acid, citric acid, and potassium bitartrate or their metabolites in human milk, the effects on the breastfed infant, or the effects on milk production.

Pediatric Use

The safety and effectiveness of PHEXXI have been established in females of reproductive potential.

Efficacy is expected to be the same for post-menarchal females under the age of 17 as for users 17 years and older. The use of PHEXXI before menarche is not indicated.

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling.

Advise the patient to read the Patient Information and FDA-approved patient labeling (Instructions for Use).

Advise the patient:

- To intravaginally administer the contents of one pre-filled single-dose applicator of PHEXXI before **each** episode of vaginal intercourse and to administer an additional dose if intercourse does not occur within one hour of administration [*see Dosage and Administration (2.1) of PHEXXI Full Prescribing Information*].
- To consult their healthcare provider for severe or prolonged genital irritation [*see Adverse Reactions (6.1) of PHEXXI Full Prescribing Information*].
- To discontinue PHEXXI if they develop a local hypersensitivity reaction [*see Adverse Reactions (6.1) of PHEXXI Full Prescribing Information*].
- To contact their health care provider if experiencing urinary tract symptoms [*see Warnings and Precautions (5.1) of PHEXXI Full Prescribing Information*].
- That PHEXXI does not protect against HIV infection and other sexually transmitted infections.

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a wholly owned subsidiary of Evofem Biosciences, Inc.,
12400 High Bluff Drive, Suite 600, San Diego, CA 92130

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U.S. Patent 6,706,276

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To report SUSPECTED ADVERSE REACTIONS, contact Evofem at toll-free phone 1-833-EVFMBIO or you may contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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