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Continuous Glucose Monitoring:

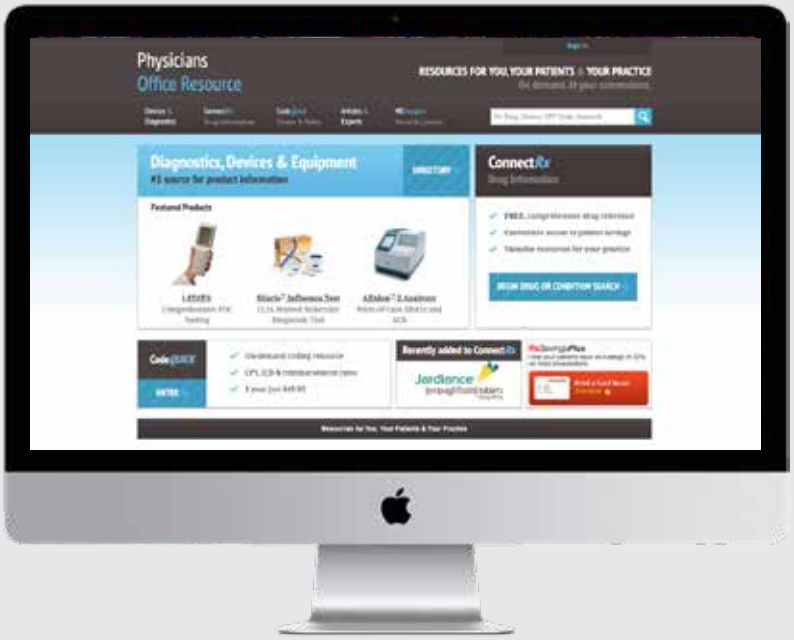
Forever Changing Diabetes Management

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CONTINUOUS GLUCOSE MONITORING:

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Many in the diabetes world consider the discovery of insulin the most significant milestone in diabetes history. While it's hard to argue with this point of view, the development of continuous glucose monitoring (CGM) systems also belongs in this same category. CGM has the potential to forever change the management of diabetes, providing patients and their physicians with a pathway to better patient outcomes.

20 **PERCEPTIONS OF RISK AND CORONAVIRUS:** Thoughts of an epidemiologist

As a physician epidemiologist and former public health official, I find myself confused by people's perceptions of risk related to coronavirus, particularly as we struggle to reopen our economy amidst a surge of cases. I'll meet an older adult with diabetes who could care less about distancing or masks, but then a healthy person in their 30's too afraid to walk outside.

24 **BEFORE YOU BUY:** Which Flu Test Is Right for Your Office?

Each year, despite forewarnings, the United States and European countries are sometimes caught off guard with a "Perfect Storm" of challenges for the influenza season. Physician offices should be stocking up on flu tests and other supplies in preparation for this year's flu season. What do they need to know before they choose a flu test?

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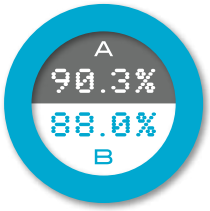


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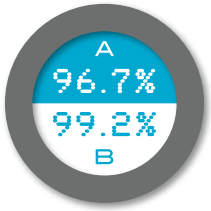
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* Compared to placebo gel; in conjunction with good ulcer care.

** Multi-center, double-blind, parallel-group placebo-controlled trial of 382 patients with type 1 or type 2 diabetes. p=0.007.

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Reference: 1. Wieman TJ, Smiell JM, Su Y. Efficacy and safety of a topical gel formulation of recombinant human platelet-derived growth factor-BB (becaplermin) in patients with chronic neuropathic diabetic ulcers. A phase III randomized placebo-controlled double-blind study. Diabetes Care. 1998;21:822-827.

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Glucose Monitor
In Range
Add Note
10m ago
108
mg
dL
300
200
100
50
90 Day Overview
20 Readings/Day
Low
Normal
High
Recent Events
Today
This Week
This Month
19:30
108 mg/dL
19:00
142 mg/dL
18:30
87 mg/dL
18:00
72 mg/dL
17:30
73 mg/dL

CONTINUOUS GLUCOSE MONITORING:

Forever Changing Diabetes Management

BY DAVID KLIFF – THE DIABETIC INVESTOR

Many in the diabetes world consider the discovery of insulin the most significant milestone in diabetes history. While it's hard to argue with this point of view, the development of continuous glucose monitoring (CGM) systems also belongs in this same category. CGM has the potential to forever change the management of diabetes, providing patients and their physicians with a pathway to better patient outcomes. It's not an overstatement to say that CGM could be the one tool that changes this ominous diabetes statistic that unfortunately has not changed in decades: more than 2/3 of patients with diabetes are NOT achieving good control.

Today, patients with diabetes have a plethora of options when it comes to the treatment of their diabetes. Thanks to the internet and now smartphones, they have instant access to information. There are thousands of websites and apps which can help the patient better manage their diabetes. Yet even with all this advanced technology and newer and better drugs, that one glaring statistic remains a constant reminder that we have yet to crack the toughest nut of all: getting the majority of patients with diabetes under good control.

In this series we will first review CGM, explaining what it is, provide an overview of the current FDA approved systems, and explain how transformative this technology can be. We'll examine how to incorporate CGM into your practice and look to the future and how this one piece of technology will forever change, for the better, the relationship between the patient with diabetes and their physician.

Before we jump into the deep end of the CGM, first, a brief history of glucose monitoring—a technology which, when first introduced back in the late 60s and early 70s, was complex to use while providing uneven results. It took 10 years or so before glucose meters became more patient friendly while providing more accurate results. At the time, these meters introduced several notable advancements, notably faster test results (5 seconds for some systems), even greater accuracy, alternate site testing, and connectivity so that data could be shared.

However, with each corresponding improvement in this technology, one indisputable fact remained: the majority of patients with diabetes were not monitoring their glucose as frequently as they should, or worse, not monitoring at all. Pundits attributed this to the fact that glucose monitoring was "painful" as the patient had to prick their finger to gather a blood sample. While we would never contend that finger pricks were an enjoyable experience, "pain" was not the real reason patients did not monitor their glucose regularly.

"... this technology is still valuable for a patient on orals alone or orals plus insulin."

The real reason was that patients did not value the information provided, plus there was no action step executed based on these results. It should surprise no one that insulin pump patients were the most frequent testers, monitoring their glucose on average eight times per day, multiple daily injection (MDI) patients were next at four times per day, and so on. Insulin-using patients not only valued this information, but needed it so they could properly dose their insulin.

Yet even with frequent testers, these point to point systems had another major limitation: they provided an incomplete picture of what was really going on. Simply put, when it comes to diabetes management, some data is better than no data, but more data is better. (And yes, we will cover how CGM systems have evolved to combine all this data with analytics.) HbA1c is widely considered the gold standard for measuring control; however, this gold standard also provides an incomplete picture of the patient.

Simply put, CGM fills in the blanks while providing a more comprehensive overview of the patient. This is the true value of CGM for both the patient and the physician as it allows a three-dimensional look. Think of it this way: CGM allows the patient and physician to see what's really going on. It can be seen whether the therapy regimen is working. It can be seen what happens after meals. It can be seen what happens while the patient is sleeping or exercising. CGM provides bright light where only darkness or limited light existed before.

CGM also has the additional benefit in that it's more patient friendly, making glucose monitoring simple. Currently there are two systems which do not require any calibrations with a conventional glucose monitor. So, the days of a patient pricking their finger are gone forever; the "pain" factor has been eliminated. All four of the currently FDA-approved systems come with connectivity therefore eliminating the need to log readings. It also allows a patient to easily share this data with their physician. Even better, CGM sensor life has improved over the years, with sensors being worn for 10 or more days.
One of the hidden benefits of CGM is it eliminates the need for the patient to carry around any testing supplies. No lancets, no test strips, nothing. This may seem like a small benefit until you talk with a patient using CGM. When it comes to diabetes management the patient has enough to worry about already and the less "stuff" they have to have with them, the better.

In summary, CGM not only provides a better, clearer picture of what's happening, it's also more patient friendly. This is why we believe that in the not so distant future, CGM will replace conventional glucose monitoring as the standard for glucose measurement. CGM systems are widely reimbursed improving patient access to this technology. The data provided by CGM is extraordinarily accurate, so much so that insulin-using patients can now dose their insulin based on data provided by their CGM without also using a conventional monitor.

Sensor insertion has become quick and relatively pain-free. And thanks to connectivity, all the heavy lifting of the analytics is also done for the patient. As we know, data by itself is just a set of meaningless numbers, but data combined with analytics leads to knowledge. Armed with this knowledge, the patient and physician can take action, action which hopefully will lead to the ultimate goal of better outcomes.

Yet what really makes CGM the most transformative technology ever invented for patients with diabetes is that it helps ALL patients no matter how they manage their diabetes. This is perhaps one the most misunderstood aspects of this revolutionary technology: it's not just for insulin-using patients, it's for all patients. Yes, there are some very obvious benefits for insulin-using patients. However, this technology is still valuable for a patient on orals alone or orals plus insulin. The difference is how each subset of patients will use and interact with their CGM. While intensively-managed insulin using patients will use CGM 24/7/365, less intensively-managed patients may only use CGM once or twice a month.

With less intensively-managed patients, CGM is first used as a discovery tool to find out what's going on. Next, it's used as a validation tool: we discovered what's going put a plan in place to handle what's going on, validate what we did, and make sure it's working. Finally, it will be used as a maintenance tool, to make sure the plan is working and that no adjustments need to be made.

The bottom line here is that CGM provides real evidence and a clear view. The patient and physician can now SEE what's going on, with no more guessing and no more relying on just HbA1c alone to make decisions. Ultimately, this is why we see CGM as the most transformative technology ever invented for patients with diabetes and their physicians. CGM brings light where only darkness existed before.



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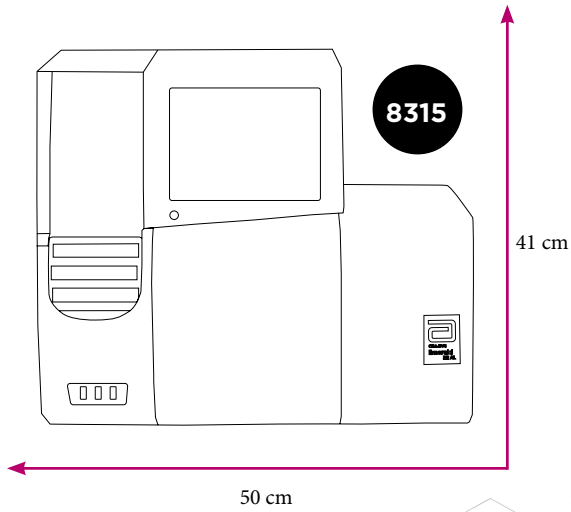
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injection 225 mg/1.5 mL



The long-acting anti-CGRP injection with the option of dosing only 4 times a year[1]*

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*"Long-acting" was defined as efficacy measured over a 12-week period following a 225 mg x 3 (675 mg) SQ dose.[1]

CGRP: calcitonin gene-related peptide; **SQ:** subcutaneous.

INDICATION

AJOVY is indicated for the preventive treatment of migraine in adults.

IMPORTANT SAFETY INFORMATION

Contraindications: AJOVY is contraindicated in patients with serious hypersensitivity to fremanezumab-vfrm or to any of the excipients.

Hypersensitivity Reactions: Hypersensitivity reactions, including rash, pruritus, drug hypersensitivity, and urticaria were reported with AJOVY in clinical trials. Most reactions were mild to moderate, but some led to discontinuation or required corticosteroid treatment. Most reactions were reported from within hours to one month after administration. If a hypersensitivity reaction occurs, consider discontinuing AJOVY and institute appropriate therapy.

Adverse Reactions: The most common adverse reactions (≥5% and greater than placebo) were injection site reactions.

Please see the Brief Summary of the Prescribing Information on the adjacent page.

Reference: 1. AJOVY® (fremanezumab-vfrm) injection Current Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.

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teva

BRIEF SUMMARY OF PRESCRIBING INFORMATION FOR AJOVY® (fremanezumab-vfrm) injection, for subcutaneous use

SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

AJOVY is indicated for the preventive treatment of migraine in adults.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

Two subcutaneous dosing options of AJOVY are available to administer the recommended dosage:

- 225 mg monthly, or
- 675 mg every 3 months (quarterly), which is administered as three consecutive subcutaneous injections of 225 mg each.

When switching dosage options, administer the first dose of the new regimen on the next scheduled date of administration. If a dose of AJOVY is missed, administer as soon as possible. Thereafter, AJOVY can be scheduled from the date of the last dose.

2.2 Important Administration Instructions

AJOVY is for subcutaneous use only.

AJOVY may be administered by healthcare professionals, patients, and/or caregivers. Prior to use, provide proper training to patients and/or caregivers on the preparation and administration of AJOVY prefilled syringe, including aseptic technique *[see Instructions for Use in full Prescribing Information]*:

- Remove AJOVY from the refrigerator. Prior to use, allow AJOVY to sit at room temperature for 30 minutes protected from direct sunlight. Do not warm by using a heat source such as hot water or a microwave. Do not use AJOVY if it has been at room temperature for 24 hours or longer.
- Follow aseptic injection technique every time AJOVY is administered.
- Inspect AJOVY for particles or discoloration prior to administration. Do not use if the solution is cloudy, discolored, or contains particles.
- Administer AJOVY by subcutaneous injection into areas of the abdomen, thigh, or upper arm that are not tender, bruised, red, or indurated. For multiple injections, you may use the same body site, but not the exact location of the previous injection.
- Do not co-administer AJOVY with other injectable drugs at the same injection site.

4 CONTRAINDICATIONS

AJOVY is contraindicated in patients with serious hypersensitivity to fremanezumab-vfrm or to any of the excipients *[see Warnings and Precautions (5.1)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Hypersensitivity reactions, including rash, pruritus, drug hypersensitivity, and urticaria, were reported with AJOVY in clinical trials. Most reactions were mild to moderate, but some led to discontinuation or required corticosteroid treatment. Most reactions were reported from within hours to one month after administration.

If a hypersensitivity reaction occurs, consider discontinuing AJOVY, and institute appropriate therapy.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are discussed in greater detail in other sections of the labeling:

- Hypersensitivity Reactions *[see Warnings and Precautions (5.1)]*

6.1 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 clinical practice.

The safety of AJOVY was evaluated in 2512 patients with migraine who received at least 1 dose of AJOVY, representing 1279 patient-years of exposure. Of these, 1730 patients were exposed to AJOVY 225 mg monthly or AJOVY 675 mg quarterly for at least 6 months, 775 patients for at least 12 months, and 138 patients for at least 15 months. In placebo-controlled clinical trials (Studies 1 and 2), 662 patients received AJOVY 225 mg monthly for 12 weeks (with or without a loading dose of 675 mg), and 663 patients received AJOVY 675 mg quarterly for 12 weeks. In the controlled trials, 87% of patients were female, 80% were White, and the mean age was 41 years.

The most common adverse reactions in the clinical trials for the preventive treatment of migraine (incidence at least 5% and greater than placebo) were injection site reactions. The adverse reactions that most commonly led to discontinuations were injection site reactions (1%). Table 1 summarizes adverse reactions reported in the 3-month placebo-controlled studies (Study 1 and Study 2), and the 1-month follow-up period after those studies.

Table 1: Adverse Reactions Occurring with an Incidence of At Least 2% for Either Dosing Regimen of AJOVY and At Least 2% Greater Than Placebo in Studies 1 and 2

Adverse Reaction	AJOVY 225 mg Monthly (n=290) %	AJOVY 675 mg Quarterly (n=667) %	Placebo Monthly (n=668) %
Injection site reactions[a]	43	45	38

[a] Injection site reactions include multiple related adverse event terms, such as injection site pain, induration, and erythema.

6.2 Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. The detection of antibody formation is highly dependent on sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors, including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to fremanezumab-vfrm in the studies described below with the incidence of antibodies in other studies to other products may be misleading. Clinical immunogenicity of AJOVY was monitored by analyzing anti-drug antibodies (ADA) and neutralizing antibodies in drug-treated patients. The data reflect the percentage of patients whose test results were positive for antibodies to AJOVY in specific assays.

In 3-month placebo-controlled studies, treatment-emergent ADA responses were observed in 6 out of 1701 (0.4%) AJOVY-treated patients. One of the 6 patients developed anti-AJOVY neutralizing antibodies at Day 84. In the ongoing long-term open-label study, ADA were detected in 1.6% of patients (30 out of 1888). Out of 30 ADA-positive patients, 17 had a neutralizing activity in their post-dose samples. Although these data do not demonstrate an impact of anti-fremanezumab-vfrm antibody development on the efficacy or safety of AJOVY in these patients, the available data are too limited to make definitive conclusions.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate data on the developmental risk associated with the use of AJOVY in pregnant women. AJOVY has a long half-life. This should be taken into consideration for women who are pregnant or plan to become pregnant while using AJOVY. Administration of fremanezumab-vfrm to rats and rabbits during the period of organogenesis or to rats throughout pregnancy and lactation at doses resulting in plasma levels greater than those expected clinically did not result in adverse effects on development *[see Animal Data]*. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. The estimated rate of major birth defects (2.2-2.9%) and miscarriage (17%) among deliveries to women with migraine are similar to rates reported in women without migraine.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

Published data have suggested that women with migraine may be at increased risk of preeclampsia and gestational hypertension during pregnancy.

Data

Animal Data

When fremanezumab-vfrm (0, 50, 100, or 200 mg/kg) was administered to male and female rats by weekly subcutaneous injection prior to and during mating and continuing in females throughout organogenesis, no adverse embryofetal effects were observed. The highest dose tested was associated with plasma exposures (AUC) approximately 2 times that in humans at a dose of 675 mg.

Administration of fremanezumab-vfrm (0, 10, 50, or 100 mg/kg) weekly by subcutaneous injection to pregnant rabbits throughout the period of organogenesis produced no adverse effects on embryofetal development. The highest dose tested was associated with plasma AUC approximately 3 times that in humans (675 mg).

Administration of fremanezumab-vfrm (0, 50, 100, or 200 mg/kg) weekly by subcutaneous injection to female rats throughout pregnancy and lactation resulted in no adverse effects on pre- and postnatal development. The highest dose tested was associated with plasma AUC approximately 2 times that in humans (675 mg).

8.2 Lactation

Risk Summary

There are no data on the presence of fremanezumab-vfrm in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for AJOVY and any potential adverse effects on the breastfed infant from AJOVY or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Clinical studies of AJOVY did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

Manufactured by:
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This Brief Summary is based on the full Prescribing Information for AJOVY AJO-004.

teva

FRE-42210 February 2020



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PERCEPTIONS OF RISK AND CORONAVIRUS:

Thoughts of an epidemiologist

BY TISTA S. GHOSH, MD, MPH

As a physician epidemiologist and former public health official, I find myself confused by people's perceptions of risk related to coronavirus, particularly as we struggle to reopen our economy amidst a surge of cases. I'll meet an older adult with diabetes who could care less about distancing or masks, but then a healthy person in their 30's too afraid to walk outside. I'll encounter a mother who is too terrified to eat outside in a restaurant but who has no fear going indoors to a nail salon or to send her kids to an overnight camp (where they live in close quarters with children from everywhere). Or I'll chat with a college student who vapes and occasionally smokes who thinks he's invincible as he heads mask-less to a party (even as we learn more about increased coronavirus risk for people who vape or smoke).

Perceptions of risk (or lack thereof) are all over the place in the U.S. This may be a result of the lack of a consistent public health voice and the mixed messages that we've witnessed throughout this pandemic. Or it may be a result of heightened emotions, whether extreme anger or fear, which can skew perceptions of risk. Or maybe it's just that people have a hard time understanding and managing risk. It's why some people are too afraid to get on an airplane, but feel just fine driving 10 miles over the speed limit on a highway in the rain. And now, as COVID-19 cases surge, this ability to judge and mitigate risk takes on increasing importance. People's perceptions of risk influence their behavior – and those behaviors directly impact both viral spread and our ability to successfully reopen our economy.

COVID-19 risk levels for people depend on a lot of factors: who they are, where they are, and what they are doing. And it can be hard for the average patient to differentiate what's scientifically accurate versus a sensational headline. I work with employees of numerous large companies, many of whom are considered essential workers, who are constantly weighing risk for themselves and their families. The analogy I've found most useful for them is the following:

When thinking about coronavirus risk, imagine that you are considering driving a car. Clearly, this is not a zero-risk activity. People die of car crashes all the time (it's a leading cause of death in the U.S.). So what goes into your decision to drive the car? Certainly, you might consider the type of car (is it in top shape or is it falling apart?), the weather conditions (a sunny day versus a snowstorm), the distance you might need to travel, your own experience as a driver (are you a teenager who just got a license or a 90-year old with eyesight and hearing loss?) and behaviors that might affect your driving (did you just have a few alcoholic beverages?). Your decision to drive will likely



vary depending on the answer to those questions, as will your level of risk. And factors that might mitigate your risk (is the car equipped with airbags and seatbelts?) might affect your decision-making as well.

So when it comes to the coronavirus, walk patients through a similar thought process:

First, ask them to establish personal risk: Are they older? Do they have underlying conditions that can put you at risk for more severe illness (diabetes, obesity, etc.?) Do they smoke or vape? Are they part of a racial or ethnic group that has had more severe outcomes?

Then ask them to consider factors related to other people or the community: Do they live with or often interact with someone who might be at high risk? Is there a lot of virus circulating in their community? Are there a lot of COVID-related hospitalizations or an increase in influenza-like illness (ILI) in their area?

Finally, consider the activity they will be engaging in, along with risk-mitigating factors: Will it be outdoors or indoors? Will they and others be wearing masks? Will they maintain six or more feet of distance? Will they be sharing drinks or other personal items? How important is this activity to them, their family, and their mental health? Is it worth the level of risk?

I try to remind my own patients: The only way to bring your risk to zero is to never leave your house or interact with anyone. Most of us will be taking calculated risks, whether it is going to the grocery store, getting a haircut, stopping at a gas station, or going for a run outside. And reopening successfully will depend on all of us judging risk more successfully. Bottom line: Outdoors is safer than indoors; masks are better than no masks. Avoid being close to people (especially face-to-face) for very long, particularly in an indoor setting. And take into account both your personal level of risk and the risk of those around you.

—

Tista Ghosh, MD, MPH is a CDC-trained epidemiologist and the former Chief Medical Officer of the state of Colorado. She was appointed to the United States Community Preventive Services Task Force but the CDC director from 2017-2019 and has served in the United States Public Health Service. She is currently the lead epidemiologist and senior Medical Director at Grand Rounds, and acts as a virtual Chief Medical Officer to numerous companies in on COVID-related return to work strategies.

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BEFORE YOU BUY:

Which Flu Test Is Right for Your Office?

Each year, despite forewarnings, the United States and European countries are sometimes caught off guard with a "Perfect Storm" of challenges for the influenza season. Physician offices should be stocking up on flu tests and other supplies in preparation for this year's flu season. What do they need to know before they choose a flu test?

Planning Ahead

So much of flu season is a guessing game, especially when trying to plan for it. The World Health Organization (WHO), the Center for Disease Control (CDC), and the Food and Drug Administration (FDA) weigh in with their recommendation to which strains should be included in the upcoming flu vaccine well before the season gets started. Their prediction on what strains should be included will dictate how effective the vaccine will be. How severe the flu season is difficult to predict ahead of time, and the key indicators used by the WHO, CDC, and others can only be obtained after flu season begins!

So, what can clinicians and distributors do to prepare? First, conducting a business assessment of what the clinicians experienced last year and looking at historical data can help dictate a plan to ensure they procure enough product.

Second, weigh the pros and cons of the tests they are currently using and tests they might be considering. Clinicians should consider the following:

- Performance—Is test sensitivity and specificity the most critical?
- Volume—How many tests does your facility perform during an average flu season?
- Ease of Use – how simple is the test to perform?
- CLIA Complexity – Does the facility require Waived Complexity (These simple and accurate tests are exempt from CLIA health and safety standards) or Moderate Complexity (These tests are more complex and have requirements for quality control, quality assurance, and more) Tests.
- Results reporting—Is it important for your facility to have an instrument-based result or visual read result, or is either one acceptable?
- Sample type—Does the test need to allow for multiple sample types (nasal, nasopharyngeal, aspirate/wash, and/or viral transport media (VTM))?
- Connectivity—Is it important for the testing device to be able to transmit the results electronically?
- Cost of the test
- The time to result
- Does the test require confirmation testing for negative results?

What's Out There?

There are several types of flu tests available on the market.

- Rapid molecular tests detect the genetic material of the virus and typically produce results in 30 minutes or less. These are considered to be more accurate than other methods.

- Rapid lateral flow immunochemical tests can be either read visually or by an instrument and are intended to detect the presence (or absence) of a target antigen in 15 minutes or less.

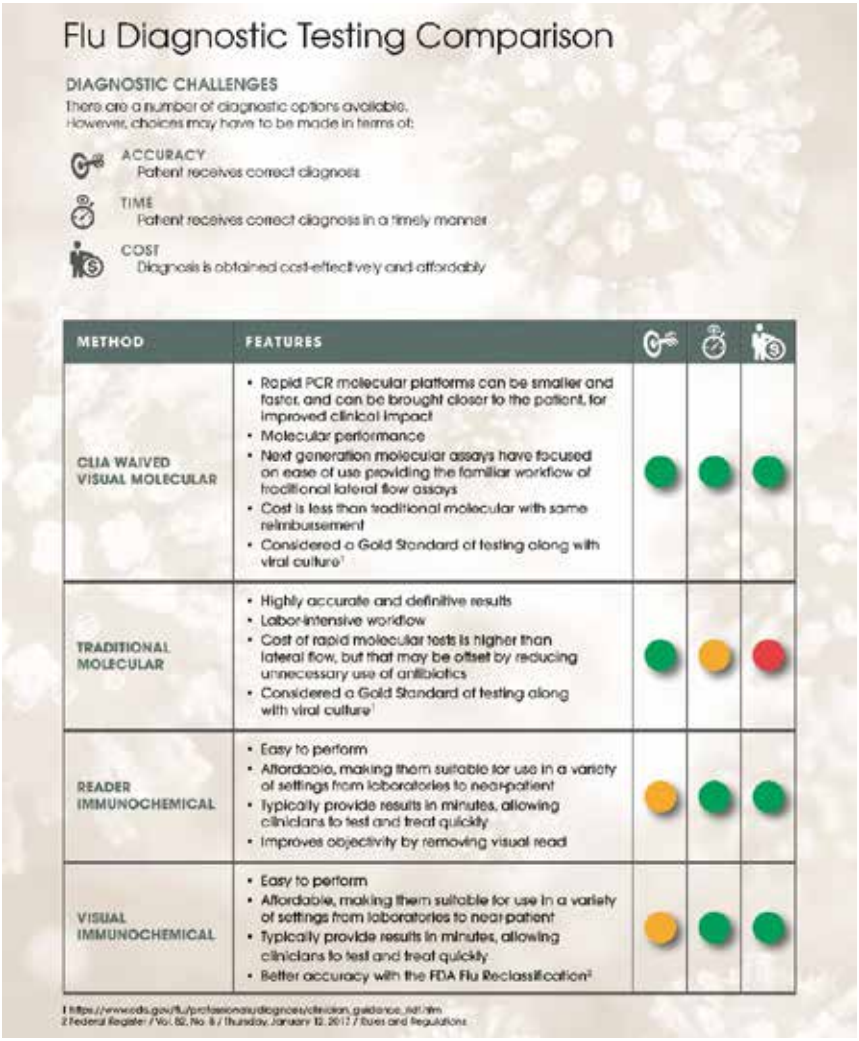
Depending on what characteristics (from above) are important to the clinician will help determine what type of test is a good fit for the facility. The manufacturer and distribution representative would be able to help guide the clinician to a product that is just right for them.

It should be noted that no flu test provides 100% accuracy. Results depend on the type of test used, the strain of virus and the integrity of the sample. It is very important when bringing on any test to review any limitations of the test, such as strain detection, any patient age limitations and performance data, along with sample collection and handling best practices and make sure that all staff is trained to provide the best in class testing.

The Importance of Testing

Due to the known performance issues surrounding the rapid tests, some physicians may argue that it's not necessary to administer a flu test in order to diagnose and treat.

Testing does not usually change how a patient will be treated for a flu diagnosis, so why bother? It turns out there are several reasons.



- Empirical treatment has a disadvantage in that many more patients are receiving treatment than actually have the flu giving rise to a possible antiviral shortage and possibly delaying the right treatment for another health issue.

- Testing patients provides valuable information to the clinician that can enable them to rule out other illnesses, helps determine a more direct therapy plan, and reduces the risk of unnecessary antiviral or antibiotics therapy, while increasing the chances that the patient will receive anti-viral therapy early when it is most effective.

- Testing will also help determine whether an outbreak of flu is occur ring. Since the implementation of rapid molecular tests and the drive by the FDA reclassification to have better RIDTs into the market clinicians can have the opportunity to utilize a highly accurate test to be more confident in the results to drive direct therapy.

How Sekisui Diagnostics Can Help

Sekisui Diagnostics offers three flu tests, using three different technologies, to help clinicians master the art of influenza testing.

The CLIA-Waived **Silaris® Influenza A&B Test** is a molecular point-of-care test utilizing polymerase chain reaction (PCR) technology providing accurate results for early diagnosis and proper management of influenza.

The CLIA-Waived **OSOMâ Ultra Plus Flu A & B Test** is rapid lateral flow qualitative test with performance equivalent to or exceeding reader devices, without the need for an instrument.

The CLIA-Waived **Acucy™ Influenza A&B Test,** used on the Acucy™ System, provides clinicians flexibility in workflow and accurate, standardized results for improved patient care. It utilizes a traditional rapid lateral flow test paired with a reader.

The 5 "Ps"

In the end, it comes down to the 5 "Ps" – Proper Preparation Prevents Poor Performance! Don't be afraid to keep stock of flu tests all year round. Understand new options—with the fear of changing strains, new technologies are more important than ever. Just remember, you have choices!

Learn more about your options at www.flutesting.com.

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phexxi™

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

Phexxi™ is a **non-hormonal** contraceptive option that regulates her vaginal pH to prevent pregnancy[1]

AVAILABLE BY PRESCRIPTION

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 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.

Patients should be counseled on the following:

- **To contact and consult with their healthcare provider for severe or prolonged genital irritation or 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.**

pHinally! There's Phexxi™

Birth control designed to meet her contraceptive needs

- **NON-HORMONAL**
- **IN THE MOMENT**
- **WORKS IMMEDIATELY**

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Phexxi™ will be available for prescription in the United States in September. For updates on the availability of Phexxi™, and for more information, visit **HCP-Phexxi.com/AvailableSoon**

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™ 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™ at HCP-Phexxi.com.

Please see Brief Summary on the following page.

REFERENCE: 1. Phexxi™ [Prescribing Information]. Evofem Biosciences, Inc: San Diego, CA; May 2020.

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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

INDICATIONS AND USAGE

PHEXXI™ 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.

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.

Manufactured for Evofem, Inc.,
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

REFDOC-000554

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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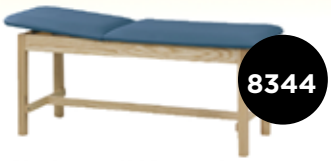
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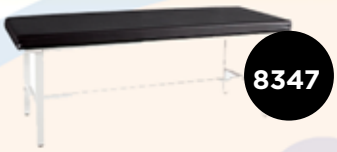
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triamcinolone acetonide extended release injectable suspension 32 mg

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INDICATION AND IMPORTANT SAFETY INFORMATION

Indication

ZILRETTA® (triamcinolone acetonide extended-release injectable suspension) is indicated as an intra-articular injection for the management of osteoarthritis pain of the knee.

Limitation of Use: The efficacy and safety of repeat administration of ZILRETTA have not been demonstrated.

Contraindication

ZILRETTA is contraindicated in patients who are hypersensitive to triamcinolone acetonide, corticosteroids, or any components of the product.

Warnings and Precautions

- **Intra-articular Use Only:** ZILRETTA has not been evaluated and should not be administered by epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal, or subcutaneous routes. Serious events have been reported with epidural and intrathecal administration of corticosteroids and none are approved for this use. ZILRETTA should not be considered safe for epidural or intrathecal administration.
- **Hypersensitivity Reactions:** Rare instances of anaphylaxis, including serious cases, have occurred in patients with hypersensitivity to corticosteroids.
- **Joint Infection and Damage:** A marked increase in pain accompanied by local swelling, restriction of joint motion, fever, and malaise are suggestive of septic arthritis. Examine joint fluid to exclude a septic process. If diagnosis is confirmed, institute appropriate antimicrobial therapy. Avoid injecting corticosteroids into a previously infected or unstable joint. Intra-articular administration may result in damage to joint tissues.
- **Increased Risk of Infections:** Infection with any pathogen in any location of the body may be associated with corticosteroid use. Corticosteroids may increase the susceptibility to new infection and decrease resistance and the ability to localize infection.
- **Alterations in Endocrine Function:** Corticosteroids can produce reversible hypothalamic-pituitary-adrenal axis suppression, with potential for adrenal insufficiency after withdrawal of treatment, which may persist for months. In situations of stress during that period, institute corticosteroid replacement therapy.
- **Cardiovascular and Renal Effects:** Corticosteroids can cause blood pressure elevation, salt and water retention, and increased potassium excretion. Monitor patients with congestive heart failure, hypertension, and renal insufficiency for edema, weight gain, and electrolyte imbalance. Dietary salt restriction and potassium supplementation may be needed.
- **Increased Intraocular Pressure:** Corticosteroid use may be associated with increased intraocular pressure. Monitor patients with elevated intraocular pressure for potential treatment adjustment.
- **Gastrointestinal Perforation:** Corticosteroid administration may increase risk of gastrointestinal perforation in patients with certain GI disorders and fresh intestinal anastomoses. Avoid corticosteroids in these patients.
- **Alterations in Bone Density:** Corticosteroids decrease bone formation and increase bone resorption. Special consideration should be given to patients with or at increased risk of osteoporosis prior to treatment.
- **Behavior and Mood Disturbances:** Corticosteroids may cause adverse psychiatric reactions. Prior to treatment, special consideration should be given to patients with previous or current emotional instability or psychiatric illness. Advise patients to immediately report any behavior or mood disturbances.

Adverse Reactions

The most commonly reported adverse reactions (incidence ≥1%) in clinical studies included sinusitis, cough, and contusions.

Please see Brief Summary of full Prescribing Information on the following page.

July 2020. Z-01227

ZILRETTA® (triamcinolone acetonide extended-release injectable suspension) for intra-articular use

BRIEF SUMMARY OF PRESCRIBING INFORMATION: See package insert for full Prescribing Information.

1. INDICATIONS AND USAGE

ZILRETTA is indicated as an intra-articular (IA) injection for the management of osteoarthritis (OA) pain of the knee.

Limitation of Use: The efficacy and safety of repeat administration of ZILRETTA have not been demonstrated.

4. CONTRAINDICATION

ZILRETTA is contraindicated in patients who are hypersensitive to triamcinolone acetonide (TA), corticosteroids (CSs), or any components of the product.

5. WARNINGS AND PRECAUTIONS

5.1 Warnings and Precautions Specific for ZILRETTA ZILRETTA has not been evaluated and should not be administered by the following routes: epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal, or subcutaneous.

5.2 Serious Neurologic Adverse Reactions With Epidural and Intrathecal Administration Serious neurologic events, some resulting in death, have been reported with epidural injection of CSs. Specific events reported include, but are not limited to, spinal cord infarction, paraplegia, quadriplegia, cortical blindness, and stroke. These serious neurologic events have been reported with and without use of fluoroscopy. Reports of serious medical events have been associated with the intrathecal route of CS administration. The safety and effectiveness of epidural and intrathecal administration of CSs have not been established, and CSs are not approved for this use. In particular, the formulation of ZILRETTA should not be considered safe to use for epidural or intrathecal administration.

5.3 Hypersensitivity Reactions Rare instances of anaphylaxis have occurred in patients with hypersensitivity to CSs. Cases of serious anaphylaxis, including death, have been reported in individuals receiving TA injection, regardless of the route of administration. Institute appropriate care if an anaphylactic reaction occurs.

5.4 Joint Infection and Damage IA injection of a CS may be complicated by joint infection. A marked increase in pain accompanied by local swelling, further restriction of joint motion, fever, and malaise are suggestive of septic arthritis. If this complication occurs and a diagnosis of septic arthritis is confirmed, institute appropriate antimicrobial therapy. Avoid injection of a CS into an infected site. Local injection of a CS into a previously infected joint is not usually recommended. Examine any joint fluid present to exclude a septic process. CS injection into unstable joints is generally not recommended. IA injection may result in damage to joint tissues.

5.5 Increased Risk of Infections Intra-articularly injected CSs are systemically absorbed. Patients who are on CSs are more susceptible to infections than healthy individuals. There may be decreased resistance and inability to localize infection when CSs are used. Infection with any pathogen (viral, bacterial, fungal, protozoan, or helminthic) in any location of the body may be associated with the use of CSs alone or in combination with other immunosuppressive agents. These infections may be mild to severe. With increasing doses of CSs, the rate of occurrence of infectious complications increases. CSs may also mask some signs of current infection. Advise patients to inform their health care provider (HCP) if they develop fever or other signs or symptoms of infection. Advise patients who have not been vaccinated to avoid exposure to chicken pox or measles. Instruct patients to contact their HCP immediately if they are exposed.

5.6 Alterations in Endocrine Function CSs can produce reversible hypothalamic-pituitary-adrenal axis suppression, with potential for adrenal insufficiency after withdrawal of treatment, which may persist for months. In situations of stress during that period (as in trauma, surgery, or illness), institute CS replacement therapy. Metabolic clearance of CSs is decreased in hypothyroid patients and increased in hyperthyroid patients.

5.7 Cardiovascular Effects CSs can cause elevations of blood pressure, salt and water retention, and increased excretion of potassium. These effects are less likely to occur with synthetic derivatives. Monitor patients with congestive heart failure (CHF) or hypertension for signs of edema, weight gain, and imbalance in serum electrolytes. Dietary salt restriction and potassium supplementation may be necessary.

5.8 Renal Effects CSs can cause salt and water retention, and increased excretion of potassium. These effects are less likely to occur with synthetic derivatives. All CSs increase calcium excretion. Monitor patients with renal insufficiency for signs of edema, weight gain, and imbalance in serum electrolytes. Dietary salt restriction and potassium supplementation may be necessary.

5.9 Increased Intraocular Pressure CS use may be associated with development or exacerbation of increased intraocular pressure. Monitor patients with elevated intraocular pressure for potential treatment adjustment.

5.10 Gastrointestinal (GI) Perforation CS administration is associated with increased risk of GI perforation in patients with certain GI disorders such as active or latent peptic ulcers, diverticulosis, diverticulitis, ulcerative colitis, and in patients with fresh intestinal anastomoses. Avoid CSs in these patients because signs of peritoneal irritation following GI perforation may be minimal or absent.

5.11 Alterations in Bone Density CSs decrease bone formation and increase bone resorption through their effect on calcium regulation and inhibition of osteoblast function. Special consideration should be given to patients with or at increased risk of osteoporosis (eg, postmenopausal women) before initiating CS therapy.

5.12 Behavioral and Mood Disturbances CS use may be associated with new or aggravated adverse psychiatric reactions ranging from euphoria, insomnia, mood swings, and personality changes to severe depression and frank psychotic manifestations. Special consideration should be given to patients with previous or current emotional instability or psychiatric illness before initiating CS therapy. Advise patients and/or caregivers to immediately report any new or worsening behavior or mood disturbances to their HCP.

6. ADVERSE REACTIONS

6.1 Clinical Trials Experience Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of a drug cannot be directly compared to rates in clinical studies of another drug and may not reflect rates observed in practice. The data below reflect exposure to a single 32mg IA injection of ZILRETTA in clinical studies in patients with moderate to severe pain due to knee OA. Clinical studies included randomized, double-blind, parallel-group, placebo- and/or active-controlled, and pharmacokinetic/pharmacodynamic studies with follow-up ranging from 6–24 weeks. 424 patients received ZILRETTA; 262 received placebo. The most commonly reported treatment-emergent adverse reactions (incidence ≥1% with ZILRETTA) in the ZILRETTA vs placebo arms were sinusitis, cough, and contusions (2% vs 1% each) and in the injected knee were joint swelling (3% vs 2%) and contusions (2% vs 1%). Overall, the incidence and nature of adverse reactions were similar to those observed with placebo.

The safety of repeat administration of ZILRETTA was evaluated in a multicenter, open-label, single-arm study in patients with OA knee pain. 179 patients received a repeat injection on or after Week 12 (median 16.6 weeks) and were followed for 52 weeks from initial injection. As assessed by adverse event rates for the periods of baseline to second dose and second dose to the comparable period after the second dose, there were higher rates of reported mild to moderate arthralgia after the second dose (16%) than after the first dose (6%). Data from this study are insufficient to fully characterize the safety of repeat administration of ZILRETTA.

6.2 Post-marketing Experience The following adverse reactions (alphabetical by body system) have been identified during post-approval use of ZILRETTA. 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. Endocrine: Increased blood glucose (in diabetic patients). General and administration site conditions: Pain, including injection-site pain or discomfort, and leg pain. Immune system: Hypersensitivity reactions including pruritis, rash, angioedema, anaphylaxis. Infections and Infestations: Septic arthritis. Musculoskeletal: Arthralgia, joint swelling or effusion, muscle spasms. Nervous system: Headache. Reproductive system: Postmenopausal vaginal bleeding (similar to a menstrual period). Skin and Subcutaneous Tissue: Pruritis.

6.3 Corticosteroid Adverse Reactions The following adverse reactions (alphabetical by body system) are from voluntary reports or clinical studies of CSs. Because some of 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. Anaphylactic reactions: Anaphylaxis including death, angioedema. Cardiovascular: Bradycardia, cardiac arrest, cardiac arrhythmias, cardiac enlargement, circulatory collapse, CHF, hypertension, fat embolism, hypertrophic cardiomyopathy in premature infants, myocardial rupture following recent myocardial infarction, pulmonary edema, syncope, tachycardia, thromboembolism, thrombophlebitis, vasculitis. Dermatologic: Acne, allergic dermatitis, cutaneous and subcutaneous atrophy, dry scaly skin, ecchymoses and petechiae, edema, erythema, hyperpigmentation, hypopigmentation, impaired wound healing, increased sweating, lupus erythematosus-like lesions, purpura, rash, sterile abscess, striae, suppressed reactions to skin tests, thin fragile skin, thinning scalp hair, urticaria. Endocrine: Decreased carbohydrate and glucose tolerance, development of Cushingoid state, glycosuria, hirsutism, hypertrichosis, increased requirements for insulin or oral hypoglycemic agents in diabetes, manifestations of latent diabetes mellitus, menstrual irregularities, secondary adrenocortical and pituitary unresponsiveness (particularly in times of stress as in trauma, surgery, or

continued on next page

illness), suppression of growth in pediatric patients. Fluid and electrolyte disturbances: Congestive heart failure (CHF) in susceptible patients, fluid retention, sodium retention. Gastrointestinal (GI): Abdominal distention, bowel/bladder dysfunction (after intrathecal administration), elevation in serum liver enzyme levels (usually reversible upon discontinuation), hepatomegaly, increased appetite, nausea, pancreatitis, peptic ulcer with possible perforation and hemorrhage, perforation of the small and large intestine (particularly in patients with inflammatory bowel disease), ulcerative esophagitis. Metabolic: Negative nitrogen balance due to protein catabolism. Musculoskeletal: Aseptic necrosis of femoral and humeral heads, calcinosis (following intra-articular [IA] or intralesional use), Charcot-like arthropathy, loss of muscle mass, muscle weakness, osteoporosis, pathologic fracture of long bones, post-injection flare (following IA use), steroid myopathy, tendon rupture, vertebral compression fractures. Neurologic/Psychiatric: Convulsions, depression, emotional instability, euphoria, headache, increased intracranial pressure with papilledema (pseudotumor cerebri) usually following discontinuation of treatment, insomnia, mood swings, neuritis, neuropathy, paresthesia, personality changes, psychiatric disorders, vertigo. After intrathecal administration—arachnoiditis, meningitis, paraparesis/paraplegia, sensory disturbances. After epidural administration—spinal cord infarction, paraplegia, quadriplegia, cortical blindness, stroke (including brainstem). Ophthalmic: Exophthalmos, glaucoma, increased intraocular pressure, posterior subcapsular cataracts, rare instances of blindness associated with periocular injections. Other: Abnormal fat deposits, decreased resistance to infection, hiccups, increased or decreased motility and number of spermatozoa, malaise, moon face, weight gain.

7. DRUG INTERACTIONS

No drug–drug interaction studies have been conducted with ZILRETTA® (triamcinolone acetonide extended-release injectable suspension). Drug interactions associated with systemic corticosteroids (CSs) include the following. Aminoglutethimide: Aminoglutethimide may lead to a loss of CS-induced adrenal suppression. Amphotericin B injection and potassium-depleting agents: When CSs are administered concomitantly with potassium-depleting agents (ie, amphotericin B, diuretics), observe patients closely for development of hypokalemia. There have been cases reported in which concomitant use of amphotericin B and hydrocortisone was followed by cardiac enlargement and CHF. Antibiotics: Macrolide antibiotics have been reported to cause a significant decrease in CS clearance. Anticholinesterases: Concomitant use of anticholinesterase agents and CSs may produce severe weakness in patients with myasthenia gravis. If possible, withdraw anticholinesterase agents at least 24 hours before initiating CS therapy. Anticoagulants, oral: Co-administration of CSs and warfarin usually results in inhibition of response to warfarin, though there have been some conflicting reports. Therefore, monitor coagulation indices frequently to maintain desired anticoagulant effect. Antidiabetics: Because CSs may increase blood glucose concentrations, dosage adjustments of antidiabetic agents may be required. Antitubercular drugs: Serum concentrations of isoniazid may be decreased. CYP3A4 inducers (eg, barbiturates, phenytoin, carbamazepine, and rifampin): Drugs that induce hepatic microsomal drug-metabolizing enzyme activity may enhance metabolism of CSs and require that the CS dosage be increased. CYP3A4 inhibitors (eg, ketoconazole): Ketoconazole, a strong CYP3A4 inhibitor, has been reported to decrease the metabolism of certain CSs by up to 60%, leading to an increased risk of CS side effects. Cholestyramine: Cholestyramine may increase the clearance of CSs. Cyclosporine: Increased activity of cyclosporine and CSs may occur when used concurrently. Convulsions have been reported with this concurrent use. Digitalis glycosides: Patients on digitalis glycosides may be at increased risk of arrhythmias due to hypokalemia. Estrogens, including oral contraceptives: Estrogens may decrease the hepatic metabolism of certain CSs, thereby increasing their effect. Nonsteroidal anti-inflammatory drugs (NSAIDs): Concomitant use of aspirin (or other NSAIDs) and CSs increases the risk of GI side effects. Aspirin should be used cautiously in conjunction with CSs in hypoprothrombinemia. Clearance of salicylates may be increased with concurrent use of CSs. Skin tests: CSs may suppress reactions to allergy-related skin tests. Vaccines: Patients on prolonged CS therapy may exhibit a diminished response to toxoids and live or inactivated vaccines due to inhibition of antibody response. CSs may also potentiate the replication of some organisms contained in live attenuated vaccines. If possible, defer routine administration of vaccines or toxoids until CS therapy is discontinued.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy Risk Summary: There are no data regarding use of ZILRETTA in pregnant women to inform a drug-associated risk of adverse developmental outcomes. Published studies on the association between CSs and fetal outcomes have reported inconsistent findings and have important methodological limitations. The majority of published literature with CS exposure during pregnancy includes oral, topical, and inhaled dosage formulations; therefore, the applicability of these findings to a single IA injection of triamcinolone acetonide (TA) is limited. In animal reproductive studies from the published literature, pregnant mice, rats, rabbits, or primates administered TA during the period of organogenesis at doses that produced exposures less than the maximum recommended human dose (MRHD) caused resorptions, decreased fetal body weight, craniofacial, and/or other abnormalities such as omphalocele. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated risk of major birth defects and miscarriage in clinically recognized pregnancies is 2–4% and 15–20%, respectively.

8.2 Lactation Risk Summary: There are no available data on presence of TA in human or animal milk, effects on the breastfed infant, or effects on milk production. However, CSs have been detected in human milk and may suppress milk production. It is not known whether IA administration of ZILRETTA could result in sufficient systemic absorption to produce detectable quantities in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ZILRETTA and any potential adverse effects on the breastfed infant from ZILRETTA.

8.3 Females and Males of Reproductive Potential CSs may result in menstrual pattern irregularities such as deviations in timing and duration of menses and an increased or decreased loss of blood.

8.4 Pediatric Use The safety and effectiveness of ZILRETTA in pediatric patients have not been established. The adverse effects of CSs in pediatric patients are similar to those in adults. Carefully observe pediatric patients, including weight, height, linear growth, blood pressure, intraocular pressure, and clinical evaluation for the presence of infection, psychosocial disturbances, thromboembolism, peptic ulcers, cataracts, and osteoporosis. Weigh potential growth effects of treatment against clinical benefits obtained and availability of treatment alternatives.

8.5 Geriatric Use Of the total number of patients administered 32mg ZILRETTA in clinical studies (N=424), 143 patients were ≥65 years old. No overall differences in safety or effectiveness were observed between elderly and younger subjects, and other reported clinical experience with TA has not identified differences in responses between elderly and younger patients. However, greater sensitivity of some older individuals cannot be ruled out.

13. NONCLINICAL TOXICOLOGY

13.2 Animal Toxicology and/or Pharmacology Single and repeat administrations (1 injection every 3 months for a total of 3 injections) of ZILRETTA in non-arthritic knee joints of healthy dogs have been studied at ~1.9xMRHD of 32mg (based on estimated drug concentrations within the knee joints). ZILRETTA microspheres were degraded by approximately 4- and 6-months post dosing in single and repeat dose studies, respectively. Single administration resulted in slightly increased incidence, severity (minimal to slight), and/or duration of microscopic changes (infiltration of macrophages, lymphocytes, plasma cells, and fibrosis) and decreased Safranin O staining (decreased proteoglycan content in knee cartilage) vs administration of an equivalent dose of immediate-release (IR) TA. These responses were mostly reversed after 6 to 9 months post injection. Repeat administration resulted in an increase in incidence, severity (minimal to slight), and duration of microscopic changes (infiltration of macrophages, lymphocytes, plasma cells, neutrophils; fibrosis; neovascularization; granulation tissue; and debris) and decreased Safranin O staining (decreased proteoglycan content in knee cartilage) vs the equivalent dose of IR TA. These local responses were still reversing at 6 months post the last injection. No effect on the animals according to observations related to gait/walking, pain/discomfort in injected knee, local swelling, local redness, or local tenderness were noted. The clinical relevance of these findings in the arthritic knee is unknown.

The Brief Summary is based on the ZILRETTA Prescribing Information
Part Number: 60-009-04, Version 4, 01/2020

Manufactured for Flexion Therapeutics, Inc.,
10 Mall Rd., Suite 301, Burlington, MA 01803
For more information, go to ZILRETTA.com or call 1-844-FLEXION (353-9466).

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The BioFire RP EZ accurately detects and identifies 14 viral and bacterial pathogens—not just Flu A and Flu B—so you can provide your patients with the right treatment, the first time. The test is easy and can be performed right in your office or clinic, with results in about an hour. The BioFire RP EZ is designed to run on a single computer/instrument configuration (EZ Configuration) of the BioFire® FilmArray® 2.0 System.

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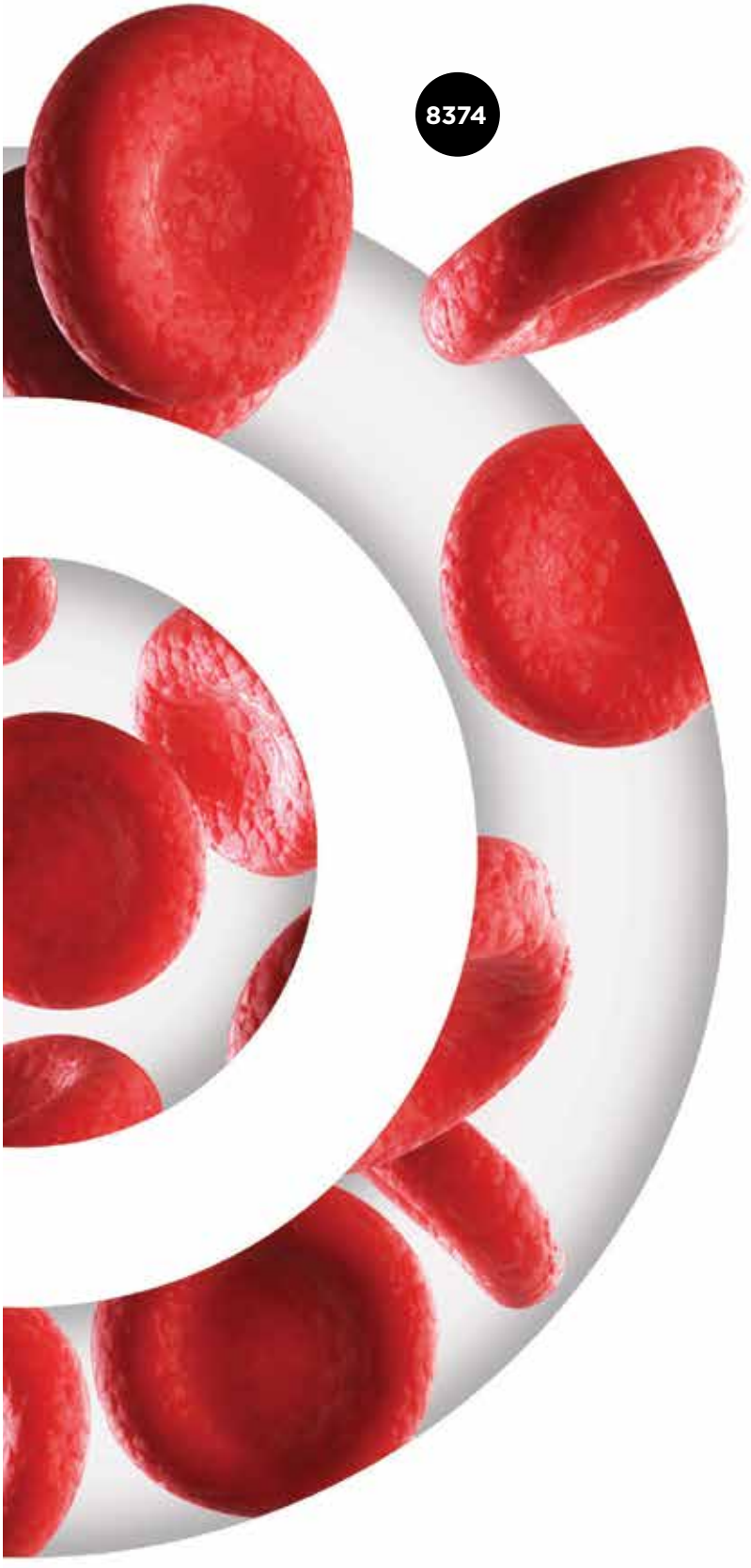
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From Sekisui Diagnostics

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*2016 Proficiency Testing Results, American Proficiency Institute, www.api-pt.com [*Piccolo Xpress*]. See cartridge information at www.pointofcare.abbott [*i-STAT*].

***i-STAT* Part No:** 04J60-20 Waived Kit, 04J48-50 Moderately Complex Kit, 06F20-20 Waived Analyzer, 04P75-03 Moderately Complex Analyzer
***Piccolo Xpress* Part No:** 07P05-50 *Piccolo Xpress* with 3YR Serv, 07P05-51 *Piccolo Xpress* with 5YR Serv

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