2021 | Issue 8

Physicians office Resource

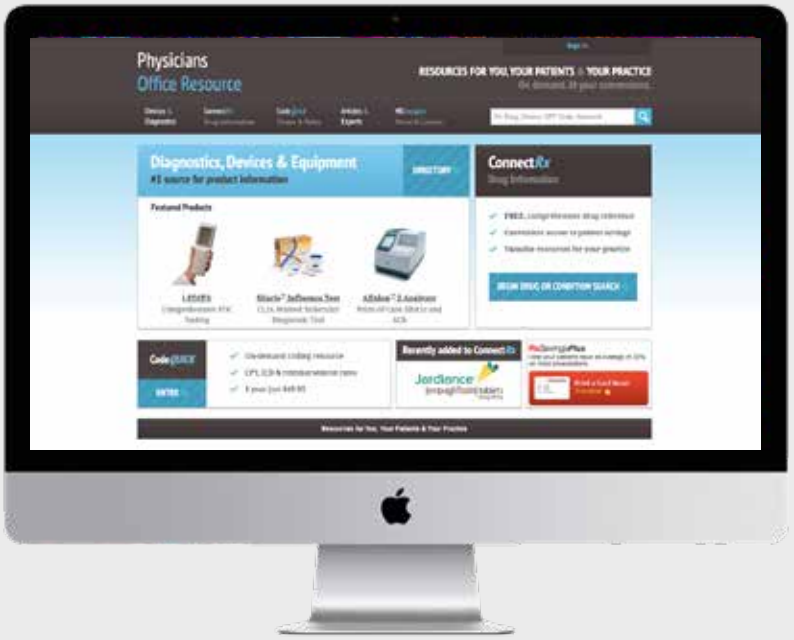
Resources for You, Your Patients, & Your Practice



MEET THE NEW GOLD STANDARD IN FIRST LEVEL OSTEOPOROSIS DIAGNOSTICS

Bindex® – the revolutionary, portable bone density scanning device

PAGE 12



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PUBLISHED BY
Medical Education Resources, LLC

PUBLISHER
Aaron R. Medaris
amedaris@physiciansofficeresource.com

CEO
Andrew C. Nimmo
acnimmo@physiciansofficeresource.com

PRESIDENT
John D. Pasquale
jpasquale@pharmaconnect.com

BUSINESS MANAGER
Marci J. Hills
mhills@physiciansofficeresource.com

TRAVEL EDITOR
Brandi L. Brower

EDITORIAL BOARD
Michael Paquin, FHIMSS
Barry Craig, MLT (NCA), CLC

STAFF WRITER
Dylan J. Chadwick

CREATIVE DIRECTOR
PRODUCTION MANAGER
Jessica Peterson

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Product Spotlight

Why Bindex® is a game-changer in osteoporosis diagnostics.

Comparable to DXA
Extensive clinical research has proven Bindex to be 90% accurate in detecting osteoporosis. It can replace nearly 70% of DXA scans for patients with suspected osteoporosis.

Fast and effective
Using safe pulse-echo ultrasound to measure cortical bone thickness, Bindex analyzes bone density in just seconds.

Easy to use anywhere
Lightweight and pocket-sized, Bindex allows patients to receive on-the-spot bone density scans in doctors' offices, hospitals and clinics and at home.

NOW YOU CAN TRIAL BINDEX AT NO COST.
To trial Bindex in your office, visit Bindex.us/launch or call (970)-306-7452.

12

WHY DXA SHOULDN'T BE YOUR ONLY OPTION

Bindex is the revolutionary, portable bone density scanning device that could be the new gold standard in first-level osteoporosis diagnostics.

28

THE ABSTRACT: MEDICAL NEWS AND RESEARCH

A new monthly column from Physicians Office Resource looking into current research and the future of medical science

35

HELPING PATIENTS HELP THEMSELVES ONLINE

There's seemingly no end to the wealth of information afforded to us on the internet, that information does come at a price: internet "quality control" is spotty at best.

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Influenza A - 96.0% (95% CI: 94.4% - 97.2%)
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CARDIOLOGY



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From Point of Care at Abbott

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piccolo xpress chemistry analyzer

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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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Abaxis 888-3355 Rev A



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9609

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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**
- Each test is processed into a fully-finished, clinically actionable report
- Easy to understand biomarkers facilitate more informed medical interventions, such as biofeedback

2 ANS Testing 9611

(can be combined with SUDOMOTOR into 1 full system)

- Takes less than 10 minutes to perform, software provides verbal cues
- Tests for autonomic balance, vascular health, physical/mental stress, peripheral nerve health and other critical hidden risk factors
- **Reimburses $170/test using 3 CPT codes**
- Provides a 1 page summary up to a full 24 page comprehensive report



3 SudoMotor Testing 9612

(can be combined with ANS into 1 full system)

- Takes 3 minutes to analyze a patients' hands and feet
- Provides a 1 page summary report
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- **Reimburses $130/test (national average)**

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From BioFire

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BD VERITOR™ PLUS SYSTEM

From BD Veritor™

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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9616



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Why DXA shouldn't be your only option

Meet Bindex® – the revolutionary, portable bone density scanning device that could be the new gold standard in first-level osteoporosis diagnostics

For over 30 years, DXA bone density scanning has been the most reliable and the most accurate way to diagnose and monitor osteoporosis. But could it be missing the mark?

Osteoporotic fractures account for more hospitalizations than breast cancer, diabetes and myocardial infarction combined.1 Yet while the entire Medicare population of around 60 million is at risk of osteoporosis, only 2.5 million DXA scans are performed annually.

While its accuracy is not in question, does the very nature of DXA – high cost, limited to those with appropriate insurance coverage, less than universal availability – ignore all but the most at-risk patients, those who might already have been identified as osteoporosis sufferers? Could there, in fact, be an easier, more inclusive yet comparably accurate way to assess bone density?

The osteoporosis diagnosis gap

The discrepancy between patients at risk for osteoporosis and the number of DXA scans performed annually may be attributed to several factors.

Patients without an osteoporosis diagnosis who are at risk because of their age, gender or other health issues may not all be eligible for a DXA scan. Younger at-risk patients may not be eligible because of their age.

Many health insurance plans cover only eligible patients (which often means patients over 65) and only for one DXA scan every two years (when osteoporosis is diagnosed) even though more frequent scanning may allow physicians to offer more timely, more customized and, potentially, more effective treatment.

Bone density scanning made easier

There is, clearly, a need for accurate bone density scanning that is both easier and more affordable for patients, especially Medicare-eligible patients. The answer may come in the form of an outwardly simple but technologically advanced hand-held device called Bindex.

Designed and manufactured by Bone Index Ltd, Bindex promises a more equitable arrangement that potentially allows more at-risk patients – of Medicare age and younger, with or without an existing diagnosis – to receive fast and accurate bone density scans in a doctor's office, clinic or any setting.

Bindex is 90% accurate in detecting osteoporosis

Extensive clinical research has proven Bindex to be 90% accurate in detecting osteoporosis which means it can replace nearly 70% of DXA scans for patients with suspected osteoporosis.

Using safe pulse-echo ultrasound, handheld Bindex measures cortical bone thickness in seconds and instantly analyzes bone density, generating a detailed yet easy-to-read report.

Better for patients – with clear advantages for doctors

Its size and portability means that Bindex can be used anywhere – in physician's offices, hospitals and clinics as well as in patients' homes and at bone density screening events. A Bindex scan costs a fraction of a DXA scan and, for many patients, particularly those who want more frequent screenings than allowed by their insurance, represents a very affordable out-of-pocket medical expense.



A Bindex scan takes seconds

Bindex means that physicians can diagnose more at-risk patients and scan more diagnosed patients more frequently, and so make timely treatment decisions and adjustments. It may also be a useful patient acquisition and retention tool, especially as patients age into Medicare, allowing physicians to keep an important source of patient revenue within their own practices.

An opportunity to trial Bindex at no cost

Bone Index Ltd, manufacturer of Bindex, is currently offering selected US-based physicians the opportunity to be part of the device's US launch by trialing Bindex with patients at no cost.

To register your interest in participating in the trial, please visit Bindex.us/launch or call (970)-306-7452.

Footnote:
1 International Osteoporosis Foundation

Designed and developed by Bone Index Ltd, a healthcare diagnostics company, Bindex is FDA-cleared and has been validated in clinical trials with several thousand patients. This revolutionary device has already screened over 1.6 million people in the US, and has 19 global patents in the US, China, Japan and major EU countries.



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The OSOM® BVBLUE® detects elevated vaginal fluid sialidase activity, an enzyme produced by bacterial pathogens associated with bacterial vaginosis including Gardnerella, Bacteroides, Prevotella and Mobiluncus. OSOM® BVBLUE® is more sensitive than Amsel criteria providing physicians with a more accurate diagnosis to treat and minimize serious health consequences such as early spontaneous preterm births and miscarriage.

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From Sekisui Diagnostics

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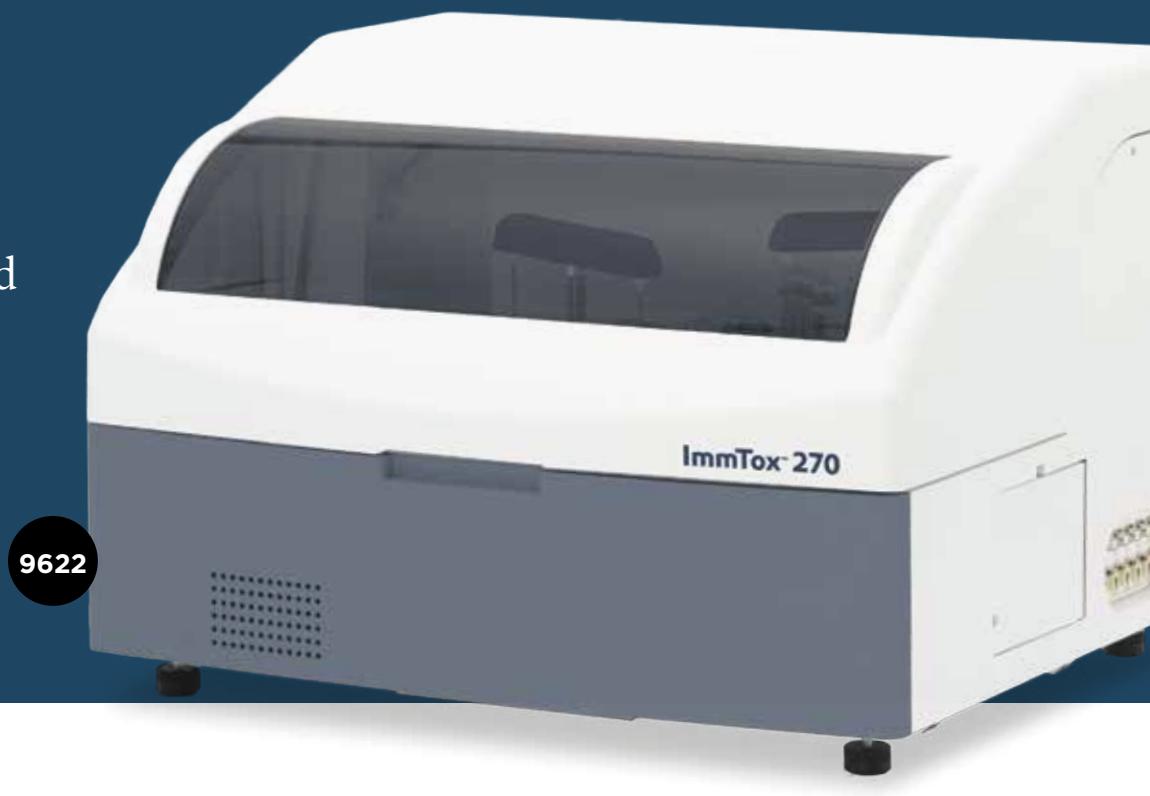
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1. Clinical Laboratory Improvement Amendments (CLIA)

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OSOM® ULTRA STREP A TEST

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From BD Veritor™

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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BIOFIRE® RESPIRATORY 2.1-EZ (RP2.1-EZ)[1] PANEL (EUA)[1]

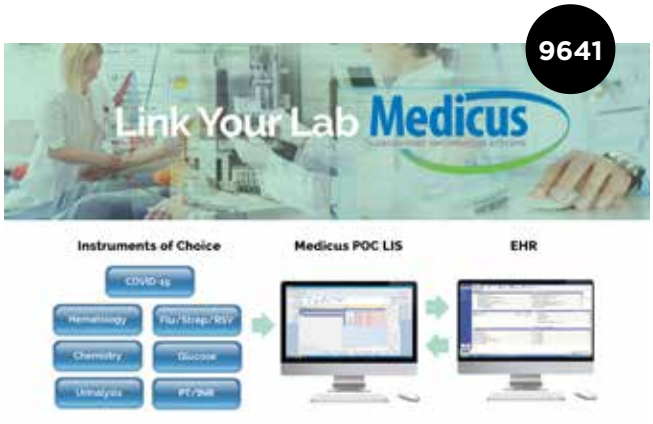
From BioFire

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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From Medicus LIS

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Contact us: 888-643-8081 sales@medicuslis.com

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This pen-like device is the perfect choice when low entry costs, portability, and precise delivery are critical to the practice. CryOmega® dispenses nitrous oxide – the coldest portable cryogen and the pinpoint tip allow physicians to effective treat the lesion site without harming healthy tissue.

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This canister-based devices is the latest advance in portable cryosurgery for the physician office. Its advanced design give doctors the option of using cones or buds to deliver the cryogen to the treatment site. There is no risk of cryogen splattering during treatment and our cryogen stays colder versus other products on the market which lead to better first time outcomes.

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CryoLab is a desk-top sized unit that delivers cryogen and employs pre-set spray times to ensure safe and effective treatment. Our lighted wand can spray the cryogen from any direction making it easier to treat all locations on the patient. CryoLab® can dispense nitrous oxide or carbon dioxide allowing physicians to treat cosmetically sensitive areas on the face, hands, and chest with less trauma and downtime.

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FOR YOUR PATIENTS WITH TARDIVE DYSKINESIA (TD)



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- Taken any time of day
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Important Information

INDICATION & USAGE

INGREZZA® (valbenazine) capsules is indicated for the treatment of adults with tardive dyskinesia.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

INGREZZA is contraindicated in patients with a history of hypersensitivity to valbenazine or any components of INGREZZA. Rash, urticaria, and reactions consistent with angioedema (e.g., swelling of the face, lips, and mouth) have been reported.

WARNINGS & PRECAUTIONS

Somnolence
INGREZZA can cause somnolence. Patients should not perform activities requiring mental alertness such as operating a motor vehicle or operating hazardous machinery until they know how they will be affected by INGREZZA.

QT Prolongation
INGREZZA may prolong the QT interval, although the degree of QT prolongation is not clinically significant at concentrations expected with recommended dosing. INGREZZA should be avoided in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval. For patients at increased risk of a prolonged QT interval, assess the QT interval before increasing the dosage.

WARNINGS & PRECAUTIONS (continued)

Parkinsonism
INGREZZA may cause parkinsonism in patients with tardive dyskinesia. Parkinsonism has also been observed with other VMAT2 inhibitors. Reduce the dose or discontinue INGREZZA treatment in patients who develop clinically significant parkinson-like signs or symptoms.

ADVERSE REACTIONS

The most common adverse reaction (≥5% and twice the rate of placebo) is somnolence. Other adverse reactions (≥2% and >Placebo) include: anticholinergic effects, balance disorders/falls, headache, akathisia, vomiting, nausea, and arthralgia.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch at **www.fda.gov/medwatch** or call 1-800-FDA-1088.

Please see the adjacent page for Brief Summary of Prescribing Information and visit Neurocrine.com/INGREZZAPI for full Prescribing Information.

REFERENCES: 1. Data on file. Neurocrine Biosciences, Inc. **2.** INGREZZA [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.

Neurocrine® BIOSCIENCES

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INGREZZA® (valbenazine) capsules
for oral use

Brief Summary: for full Prescribing Information and Patient Information, refer to package insert.

INDICATION AND USAGE
INGREZZA® (valbenazine) capsules is indicated for the treatment of adults with tardive dyskinesia.

CONTRAINDICATIONS
INGREZZA is contraindicated in patients with a history of hypersensitivity to valbenazine or any components of INGREZZA. Rash, urticaria, and reactions consistent with angioedema (e.g., swelling of the face, lips, and mouth) have been reported.

WARNINGS AND PRECAUTIONS
Somnolence

INGREZZA can cause somnolence. Patients should not perform activities requiring mental alertness such as operating a motor vehicle or operating hazardous machinery until they know how they will be affected by INGREZZA.

QT Prolongation

INGREZZA may prolong the QT interval, although the degree of QT prolongation is not clinically significant at concentrations expected with recommended dosing. In patients taking a strong CYP2D6 or CYP3A4 inhibitor, or who are CYP2D6 poor metabolizers, INGREZZA concentrations may be higher and QT prolongation clinically significant. For patients who are CYP2D6 poor metabolizers or are taking a strong CYP2D6 inhibitor, dose reduction may be necessary. For patients taking a strong CYP3A4 inhibitor, reduce the dose of INGREZZA to 40 mg once daily. INGREZZA should be avoided in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval. For patients at increased risk of a prolonged QT interval, assess the QT interval before increasing the dosage.

Parkinsonism

INGREZZA may cause parkinsonism in patients with tardive dyskinesia. Parkinsonism has also been observed with other VMAT2 inhibitors. In the 3 placebo-controlled clinical studies in patients with tardive dyskinesia, the incidence of parkinson-like adverse events was 3% of patients treated with INGREZZA and <1% of placebo-treated patients. Postmarketing safety reports have described parkinson-like symptoms, some of which were severe and required hospitalization. In most cases, severe parkinsonism occurred within the first 2 weeks after starting or increasing the dose of INGREZZA. Associated symptoms have included falls, gait disturbances, tremor, drooling, and hypokinesia. In cases in which follow-up clinical information was available, parkinson-like symptoms were reported to resolve following discontinuation of INGREZZA therapy. Reduce the dose or discontinue INGREZZA treatment in patients who develop clinically significant parkinson-like signs or symptoms.

ADVERSE REACTIONS
The following adverse reactions are discussed in more detail in other sections of the labeling:

- Hypersensitivity
- Somnolence
- QT Prolongation
- Parkinsonism

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.

Variable and Fixed Dose Placebo-Controlled Trial Experience

The safety of INGREZZA was evaluated in 3 placebo-controlled studies, each 6 weeks in duration (fixed dose, dose escalation, dose reduction), including 445 patients. Patients were 26 to 84 years of age with moderate to severe tardive dyskinesia and had concurrent diagnoses of mood disorder (27%) or schizophrenia/schizoaffective disorder (72%). The mean age was 56 years. Patients were 57% Caucasian, 39% African-American, and 4% other. With respect to ethnicity, 28% were Hispanic or Latino. All subjects continued previous stable regimens of antipsychotics; 85% and 27% of subjects, respectively, were taking atypical and typical antipsychotic medications at study entry.

Adverse Reactions Leading to Discontinuation of Treatment

A total of 3% of INGREZZA treated patients and 2% of placebo-treated patients discontinued because of adverse reactions.

Common Adverse Reactions

Adverse reactions that occurred in the 3 placebo-controlled studies at an incidence of ≥2% and greater than placebo are presented in Table 1.

Table 1: Adverse Reactions in 3 Placebo-Controlled Studies of 6-week Treatment Duration Reported at ≥2% and >Placebo

Adverse Reaction[1]	INGREZZA (n=262) (%)	Placebo (n=183) (%)
General Disorders		
Somnolence (somnolence, fatigue, sedation)	10.9%	4.2%
Nervous System Disorders		
Anticholinergic effects (dry mouth, constipation, disturbance in attention, vision blurred, urinary retention)	5.4%	4.9%
Balance disorders/fall (fall, gait disturbance, dizziness, balance disorder)	4.1%	2.2%
Headache	3.4%	2.7%
Akathisia (akathisia, restlessness)	2.7%	0.5%
Gastrointestinal Disorders		
Vomiting	2.6%	0.6%
Nausea	2.3%	2.1%
Musculoskeletal Disorders		
Arthralgia	2.3%	0.5%

[1] Within each adverse reaction category, the observed adverse reactions are listed in order of decreasing frequency.

Other Adverse Reactions Observed During the Premarketing Evaluation of INGREZZA

Other adverse reactions of ≥1% incidence and greater than placebo are shown below. The following list does not include adverse reactions: 1) already listed in previous tables or elsewhere in the labeling, 2) for which a drug cause was remote, 3) which were so general as to be uninformative, 4) which were not considered to have clinically significant implications, or 5) which occurred at a rate equal to or less than placebo.

Endocrine Disorders: blood glucose increased

General Disorders: weight increased

Infectious Disorders: respiratory infections

Neurologic Disorders: drooling, dyskinesia, extrapyramidal symptoms (non-akathisia)

Psychiatric Disorders: anxiety, insomnia

During controlled trials, there was a dose-related increase in prolactin. Additionally, there was a dose-related increase in alkaline phosphatase and bilirubin, suggesting a potential risk for cholestasis.

Postmarketing Experience

The following adverse reactions have been identified during post-approval use of INGREZZA that are not included in other sections of labeling. 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.

Immune System Disorders: hypersensitivity reactions (including allergic dermatitis, angioedema, pruritis, and urticaria)

Skin and Subcutaneous Tissue Disorders: rash

DRUG INTERACTIONS
Drugs Having Clinically Important Interactions with INGREZZA

Table 2: Clinically Significant Drug Interactions with INGREZZA

Monoamine Oxidase Inhibitors (MAOIs)	
Clinical Implication:	Concomitant use of INGREZZA with MAOIs may increase the concentration of monoamine neurotransmitters in synapses, potentially leading to increased risk of adverse reactions such as serotonin syndrome, or attenuated treatment effect of INGREZZA.
Prevention or Management:	Avoid concomitant use of INGREZZA with MAOIs.
Examples:	isocarboxazid, phenelzine, selegiline
Strong CYP3A4 Inhibitors	
Clinical Implication:	Concomitant use of INGREZZA with strong CYP3A4 inhibitors increased the exposure (Cmax and AUC) to valbenazine and its active metabolite compared with the use of INGREZZA alone. Increased exposure of valbenazine and its active metabolite may increase the risk of exposure-related adverse reactions.
Prevention or Management:	Reduce INGREZZA dose when INGREZZA is coadministered with a strong CYP3A4 inhibitor.
Examples:	itraconazole, ketoconazole, clarithromycin
Strong CYP2D6 Inhibitors	
Clinical Implication:	Concomitant use of INGREZZA with strong CYP2D6 inhibitors increased the exposure (C_{max} and AUC) to valbenazine's active metabolite compared with the use of INGREZZA alone. Increased exposure of active metabolite may increase the risk of exposure-related adverse reactions.
Prevention or Management:	Reduce INGREZZA dose when INGREZZA is coadministered with a strong CYP2D6 inhibitor.
Examples:	paroxetine, fluoxetine, quinidine
Strong CYP3A4 Inducers	
Clinical Implication:	Concomitant use of INGREZZA with a strong CYP3A4 inducer decreased the exposure of valbenazine and its active metabolite compared to the use of INGREZZA alone. Reduced exposure of valbenazine and its active metabolite may reduce efficacy.
Prevention or Management:	Concomitant use of strong CYP3A4 inducers with INGREZZA is not recommended.
Examples:	rifampin, carbamazepine, phenytoin, St. John's wort[1]
Digoxin	
Clinical Implication:	Concomitant use of INGREZZA with digoxin increased digoxin levels because of inhibition of intestinal P-glycoprotein (P-gp).
Prevention or Management:	Digoxin concentrations should be monitored when coadministering INGREZZA with digoxin. Increased digoxin exposure may increase the risk of exposure-related adverse reactions. Dosage adjustment of digoxin may be necessary.

[1] The induction potency of St. John's wort may vary widely based on preparation.

Drugs Having No Clinically Important Interactions with INGREZZA

Dosage adjustment for INGREZZA is not necessary when used in combination with substrates of CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2E1, or CYP3A4/5 based on *in vitro* study results.

OVERDOSAGE
Human Experience

The pre-marketing clinical trials involving INGREZZA in approximately 850 subjects do not provide information regarding symptoms with overdose.

Management of Overdosage

No specific antidotes for INGREZZA are known. In managing overdose, provide supportive care, including close medical supervision and monitoring, and consider the possibility of multiple drug involvement. If an overdose occurs, consult a Certified Poison Control Center (1-800-222-1222 or www.poison.org).

For further information on INGREZZA, call 84-INGREZZA (844-647-3992).

Neurocrine® BIOSCIENCES

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CP-VBZ-US-0203v5 05/2020

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With reduced budgets, shrinking laboratory space and staffing challenges, many laboratories need a solution that lets them work smarter with less. The CELL-DYN Emerald 22 AL is a full performance, automated optical 5-part differential analyzer that delivers smarter results for small to midsize clinical laboratories.

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- Decreasing manual entry errors and increasing compliance by use of barcoded reagents
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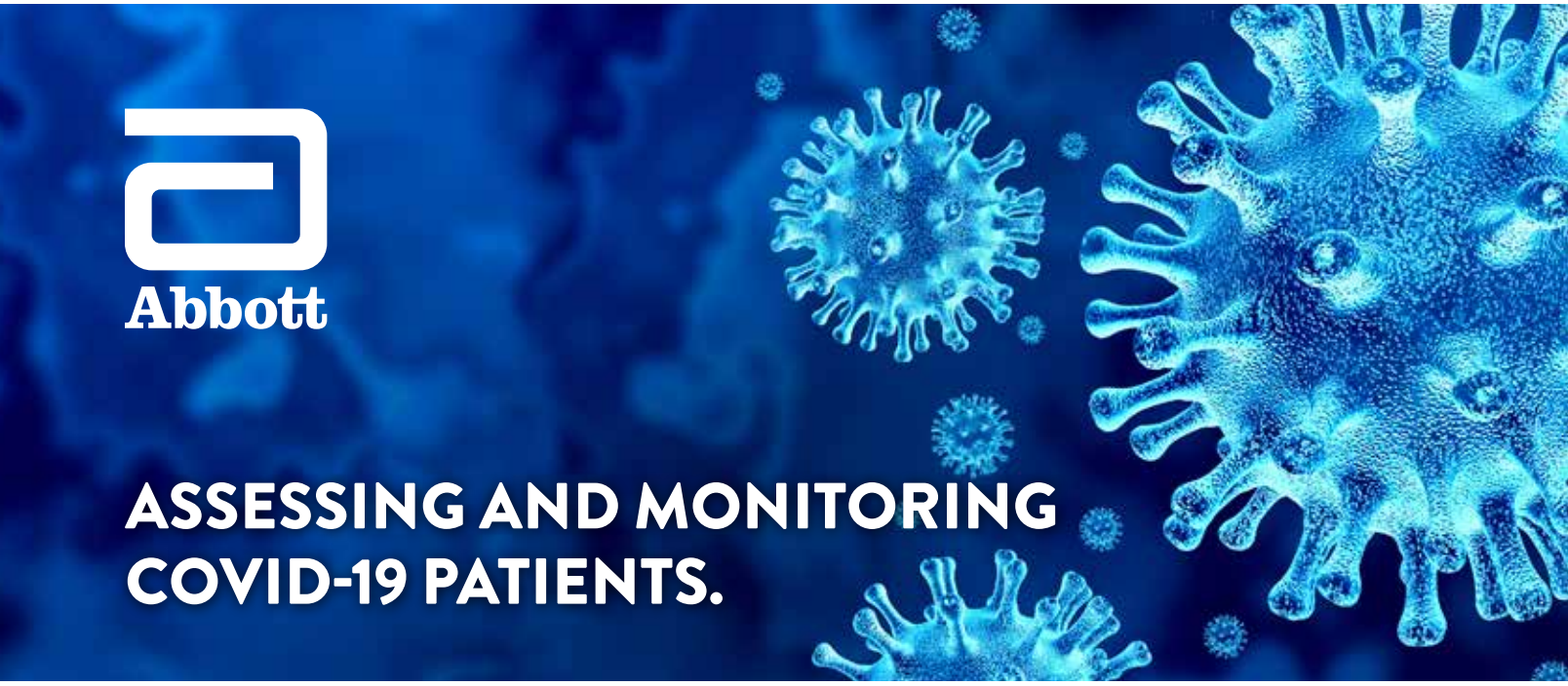
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ASSESSING AND MONITORING COVID-19 PATIENTS.

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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For *in vitro* diagnostic use only.

The Piccolo Xpress does not directly diagnose COVID-19.

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Get accurate results in minutes, at the point-of-care.

SEE A LIST OF KEY PICCOLO XPRESS PANELS ON BACK.



KEY PICCOLO XPRESS PANELS.

CLIA-WAIVED PANELS



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MetLyte 8
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Liver Panel Plus
ALB, ALP, ALT, AMY, AST, GGT, tBIL, TP

*Calculated

MODERATELY COMPLEX PANELS



BioChemistry Panel Plus
ALB, ALP, ALT, AMY, AST, BUN, Ca, Crea, Glu, GGT, TP, UA, CRP, eGFR*



MetLyte Plus CRP
Na+, K+, Cl-, tCO_2, BUN, Crea, Glu, CK, CRP, eGFR*



Hepatic Function Panel
ALB, ALP, ALT, AST, tBIL, dBIL, TP

To learn how the Piccolo Xpress portable diagnostic analyzer can help transform your patient care, contact your Abbott Point of Care Representative or visit www.pointofcare.abbott

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The Abstract:

Medical News and Research Update

Blood Markers Indicating Labor is Approaching Identified

Researchers at Stanford University School of Medicine have identified for the first-time blood markers indicating when a pregnant women will go into labor. The study, which was published in Science Translational Medicine, gives insights on how labor begins, by analyzing immune and other biological signals in a blood sample. The study's lead author, Ina Stelzer, PhD, said, "We found a transition from 'progressing pregnancy' to a 'pre-labor' phase that happens two to four weeks before the mom goes into labor...We've identified a novel way to use the maternal blood to predict when a mother will go into labor. This prediction is independent from the duration of pregnancy."1 Brice Gaudilliere, MD, PhD, and the study's senior author said, "Clinicians are good at estimating gestational age, which measures the development of the fetus. But there is a disconnect between this timing and when labor starts, because whether the baby is ready is only one factor in the onset of labor, the other part of the equation is the mother."1 The study focused on 63 women during the last 100 days of pregnancy. Blood samples were taken two to three time prior to birth and each sample was analyzed for 7,142 metabolic, protein, and single-cell immune features. Researchers utilizing mathematical modeling where able to identify blood markers that best predicted the onset of labor. Current results though imprecise, about a five-week window, could lay the foundation for a more accurate clinical blood test.

New Technique to Treat Middle Ear Infections

Middle ear infections affect more than 80% of children. Current treatment methods often include prescribing antibiotics; however research has shown that in 30% of middle ear infection cases, antibiotics don't work. Also due to the prevalence of middle ear infections, overuse of antibiotics can lead to antibiotic resistant bacteria. That's why results coming from a study funded by the National Science Foundation is providing hope for another treatment option. Researchers at the University of Illinois Urbana-Champaign have developed a 3D printed device to inactivate a common bacterium that causes middle ear infections. The 3D printed device generates plasma composed of charged particles and reactive molecules which can inactivate a variety of pathogens. Researchers in this project decided to try and penetrate the biofilm of the bacteria within the ear. Helen Nhuyen, an engineer who was part of the study, stated, "Biofilms are very dense, making it difficult for the antibiotics to penetrate. Our idea was that if we could disrupt the structure of the biofilm, we could increase the penetration of the antibiotics."3 The research has been tested on rats and found after 15 minutes of treatment, bacteria was inactivated with no results of physical damage to the rat eardrum. The results suggest that this method could be used to treat middle ear infections in humans.

"New Generation" Artificial Heart Implanted in Patient – First in United States

Drs. Jacob Schroder and Carmelo Milano lead a surgical team at Duke University Hospital which successfully implanted a new generation artificial heart. The 39-year-old man in which the artificial heart was implanted suffered from advanced biventricular heart failure. The artificial heart developed by CARMAT is intended to replace the ventricles of the native heart in patients and is currently approved to begin studies in the US. "Because of the shortages of donor hearts, many patients die while waiting for a heart transplant...we are hopefully for new options to help these patients," said Dr. Schroder. Dr. Milano continued, "We are encouraged that our patient is doing so well after the procedure. As we evaluate this device, we are both excited and hopeful that patients who otherwise have few to no options could have a lifeline."2

Calcium Regulating Heart Protein Could Lead to New Treatment for Heart Failure

It has long been known that calcium plays a vital role in bone, muscle, and heart health. Regarding heart health, calcium surge and diminish during and in between normal heart beats. Scientist also know that mitochondria depend on calcium to help produce energy that in return keeps the cell alive.

In a recent study published in Nature5, an international study lead by researchers from the University of Utah sought to better understand the specific role of mitochondria and it's relation to calcium signaling within heart cells. Researchers observed that when the signaling pathway for protein, VDAC2 was disrupted severe impairment of heart cell contraction occurred; thus making it harder for the heart to pump blood to the body. Stavrose Drakos, MD, PhD, senior author on the study, said, "Based on our human and laboratory research, it appears that if VDAC2 is not working properly, then everything in the heart can cascade downward from there. If we can figure out ways to help this protein do its job again, then it's possible that we might be able to address heart failure far earlier in the disease process."4 Researchers are hopeful this will open the way for therapeutic drugs to alleviate heart failure by targeting VDAC2.

Sources

Blood Markers Indicating Labor is Approaching are Identified
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Children with Type 2 Diabetes Face Dire Future

Type 2 diabetes in youth is increasing not just within the United States, but throughout the world. Up until now, little was known about the direct impact that type 2 diabetes would have on these youth as they entered adulthood. Now, thanks to a 15 year study, researchers have a better understanding of the dire effects this childhood disease will have on adults. According to a study published in the New England Journal of Medicine, "among participants who had onset of type 2 diabetes in youth, the risk of complications, including microvascular complications, increased steadily over time and affected most participants by the time of young adulthood."6 500 participants were evaluated with a mean age of 26.4±2.8 years, after being diagnosed with T2D around the age of 13 showed the following complications:

Cumulative incidences of hypertension = 67.5%
Incidence of dyslipidemia = 51.6%
Incidence of kidney disease was 54.8%
Incidence of nerve disease 32.4%
Prevalence of retinal disease increased from 13.7% in 2010/2011 to 51% in 2017/2018

The study also noted that "complications were more common among participants of minority race and ethic group and among those with hyperglycemia, hypertension, and dyslipidemia."6

Certain Types of Body Fat Decrease Gray Brain Matter

Gray brain matter is named for its grayish-pink color and is home to neural cell bodies, axon terminal, dendrites, and all never synapses. Gray matter is also essential in learning, memory, muscle control, and cognitive function. So, when researchers at the University of South Australia found that some types of obesity lead to a reduction in gray matter in the brain, alarms were raised. Lead author of the study, Anwar Mulugeta, PhD., said "We found that people with higher levels of obesity, especially those with metabolically unfavorable and neutral adiposity subtypes, had much lower levels of gray brain matter, indicating that these people may have compromised brain function, which needed further investigation."8 The study found that for, "every extra 6.6 lbs. of body weight in a person of average height, the amount of gray matter decreased by .3%"8 Dr. Mulugeta lead author of the study stated, "However, we did not find conclusive evidence to link a specific obesity subtype with dementia or stroke. Instead, our study suggests the possible role of inflammation and metabolic abnormalities and how they can contribute to obesity and gray matter volume reduction."8



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Simple to use and easy to maintain with a zero maintenance concept, the Micros ES 60 is a small tabletop hematology analyzer with an integrated data management system. The analyzer provides a CBC with 3-part differential result in less than 60 seconds using only 10 µL of sample. Connect to the Lite^{DM} Patient Data Management System for an affordable way to consolidate patient results to one report.

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PENTRA 60 C+ HEMATOLOGY ANALYZER WITH 5-PART DIFFERENTIAL

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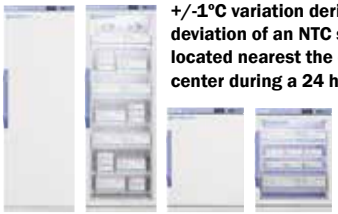
Now you can have the same results hospitals and reference labs provide in a small, benchtop analyzer. The Pentra 60 C+ hematology analyzer provides a CBC with 5-part differential result using proprietary technology that ensures an accurate count and differential on the first run. Reduce repeats and reflex to the microscope with Pentra hematology technology.

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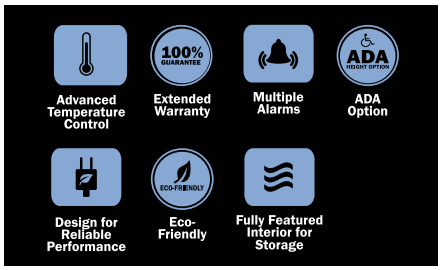


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ARG1PV	1 cu.ft.	21.5"	17.5"	20"	Glass	**878.00**
ARS3PV	3 cu.ft.	33.75"	18.5"	19"	White	**965.00**
ARG3PV	3 cu.ft.	33.75"	18.5"	19.5"	Glass	**969.00**
ARS6PV	6 cu.ft.	32.5"	23.5"	24.5"	White	**1,060.00**
ARG6PV	6 cu.ft.	32.5"	23.5"	25"	Glass	**1,072.00**
ARS8PV	8 cu.ft.	50"	23.38"	24.5"	White	**1,284.00**
ARG8PV	8 cu.ft.	50"	23.38"	25"	Glass	**1,349.00**
ARS12PV	12 cu.ft.	61.75"	23.38"	24.5"	White	**1,788.00**
ARG12PV	12 cu.ft.	61.75"	23.38"	25"	Glass	**1,801.00**
ARS15PV	15 cu.ft.	72"	23.5"	24.5"	White	**1,970.00**
ARG15PV	15 cu.ft.	72"	23.5"	25"	Glass	**1,983.00**

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	**2,466.00**
ARG23ML	23 cu.ft.	83.75	27.5	31	(1) Glass	**2,811.00**
ARS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	**3,634.00**
ARG49ML	49 cu.ft.	83.75	55.25	31	(2) Glass	**4,186.00**

Pharma-Lab Freezers

Accucold	Capacity	Height	Width	Depth	Door	PRICE
AFS23ML	23 cu.ft.	83.75	27.5	31	(1) Stainless	**2,804.00**
AFS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	**4,299.00**

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Refrigerator: Add the number of doses on hand (current inventory) from your last order form.

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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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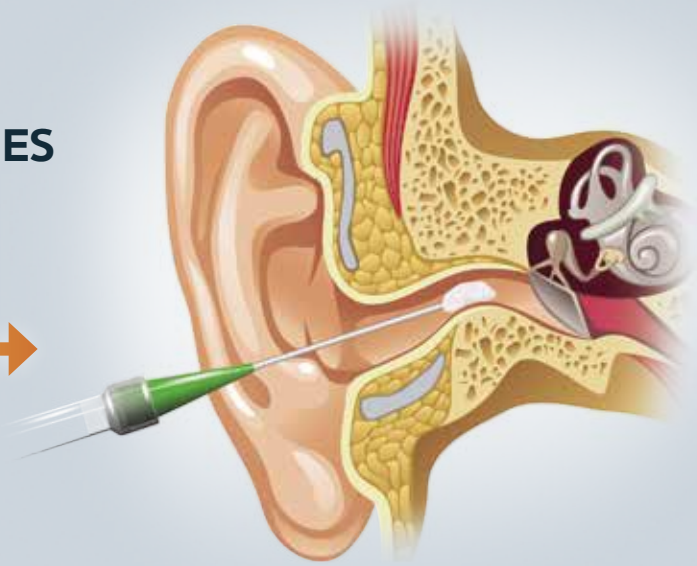
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OTIPRIO uses proprietary formulation technology

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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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HELPING PATIENTS HELP THEMSELVES ONLINE

BY DLYAN CHADWICK

These days, virtually any brick and mortar service has its own internet doppleganger. One can attain a college degree by attending online classes, stream movies directly from the source and of course, there's Wikipedia, the online staple that's put the final nail in the coffin of the door-to-door Encyclopedia industry. And while there's seemingly no end to the wealth of information afforded to us on the internet, that information does come at a price: internet "quality control" is spotty at best.

Now, that's well and good, likely entry level information to anyone who's ever written a term paper or sought out unbiased information in a Honda forum...but then again, internet literacy isn't always a straightforward metric. In an article by Tanya Fenke MD, (Dr. Google Should Be Sued for Malpractice. Here's Why), the author illustrates the inherent problem of taking all our health concerns to Google, namely that internet sources quickly become outdated, are biased towards their benefactors and constituents, aren't often written by healthcare professionals and often lack traceable references. In fact, as the title dictates, she suggests that if Google were a physician, he or she should be sued for malpractice, based on the number of problems that disseminating false information causes (no word on Dr. Pepper and Dr. Feelgood's prospects at the time of publication).

While I wholeheartedly agree with Fenke's assessment, that Google, or an internet search, isn't a sustainable replacement for actual medical advice from an actual, living, breathing medical professional, I also realize the dilemma of Google's involvement in everything. The trends of internet ubiquity aren't going to slow, nor will Google's lumbering ascent into total control of the internet cease. This isn't glass half-empty philosophizing either, just the acceptance that if/when (more like when) the machines finally do take over, we can assume Google will be in the mix somewhere.

Instead, it's becoming important for physicians to not only be the conduits towards viable health information, but also to help patients establish good searching habits for when they come across health information on their own time. Physicians cannot dictate what their patients will read and see outside of the office, but by giving them the tools to sniff out what's good and what probably needs a second opinion, they greatly reduce the number of faulty accidents and misunderstandings.

Look for Recent Content

Health information is subject to ongoing developments and research, on micro and macro scales. What was once the de-rigeur health fad or yesterday might have been proven total bunk today, and vice versa. In that regard, information on the internet can run a little bit dicey since (theoretically) anything put online stays online forever. Encourage patients to check their sources and to be wary of any sources from more than a few years old, particularly if it's dispensing health advice. Even if the information has stayed the same, credible and reputable outlets will be sure to keep things current anyway.

Additionally, the idea of timeliness opens up the discussion for physician blogging and social media, a great way to create relevant and reputable content quickly, to update on information that is changing and to just generally maintain a current channel of communication. Patients should also be wary of

"...It's becoming important for physicians to not only be the conduits towards viable health information, but also to help patients establish good searching habits for when they come across health information on their own time."

information that doesn't contain any dates as there's no way to determine how recently it was obtained and published.

Objectivity and Bias

It can be difficult to look objectively at one's own symptoms, especially when emotions are running strong and influencing one's actions. In this regard, internet searching along various strings of keywords can push the user towards a "self-diagnosis" that is biased or at the very least a little skewed. This also introduces what I call the "WebMD" effect in which a person goes down the internet rabbit-hole of reading all symptoms associated with a certain disorder and slowly convinces themselves that they indeed have the disorder. No one is immune to momentary flashes of anxious grandiosity.

Furthermore, there's a wealth of "for profit" sources out there, posing as viable health professionals, even when they're not. Wary patients should be mindful of any sites with corporate sponsors, as the information contained may just be a sideways plug to get you to buy a miracle product or to sell you on an affliction you don't actually have. Solid health information is a right, and shouldn't market you towards buying anything new.

Experience and Credibility

It goes without saying, but a number of those dispensing health care information are just writers….not doctors (this one included). In this regard, knowing exactly where a source comes from can be what will set off the "nonsense meter" right away. Patients should look for the credentials of an author who's dispensing health care information, ensuring that they're actual, medically licensed doctors. Even so, it's not uncommon for professionals to get their articles ghost written by off-site writers. Patients should assume that any information coming from a source that doesn't identify as a physician should probably not be regarded at all, and those that come from doctors, should be carefully vetted before following up on them.

Sources and Citations

In print, most must cite their sources, but on the internet, and it can be a bit more difficult to truly regulate this principle. If a site doesn't cite the sources of its claims, or if they're especially absolute or broad and sweeping, one should maintain their skeptic senses a bit. Information can be sensationalized to drive ratings and page views to a site, and often take claims and facts out of context, specifically to fit their own content agenda. If a site doesn't provide sources for its health care advice, isn't from a health sanctioned organization or contains many sources from less credible sources, patients shouldn't accept the information sight unseen. Remember, if a site doesn't want readers to know where they got their stories, at best they likely don't have anyone's best interests in mind and at worst, could be hiding something.

Encourage the In-Person Follow Up

Fortunately, physicians still have the ultimate, and most credible, say in directing patients towards quality health care information. Besides endowing them with a dose of healthy skepticism towards online health information (and let's be honest, it's a good trait to have in an election year too), it's important to remind them that they can always follow up directly with you, a primary health care source, about anything unclear. Not only does this type of outreach send the message that you're there to help and guide them in their healthcare journey, but also establishes a precedent for always checking up with a qualified source before taking anything to heart.

Ultimately, we shouldn't recognize Google as anything even remotely like a doctor and should recast it for what it really is: "a huge repository of information, scrupulously indexed and largely unregulated." Patients and users still have the power.

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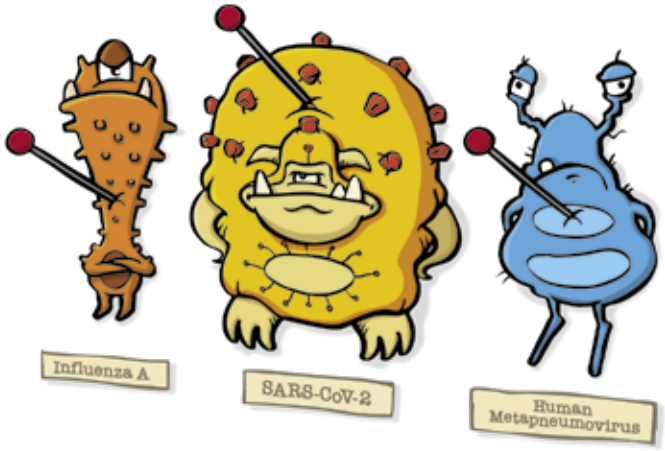


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