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Physicians office Resource

Resources for You, Your Patients, & Your Practice



PREPARING FOR YOUR LAB INSPECTION
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STRUCTURING YOUR STAFF MODEL:

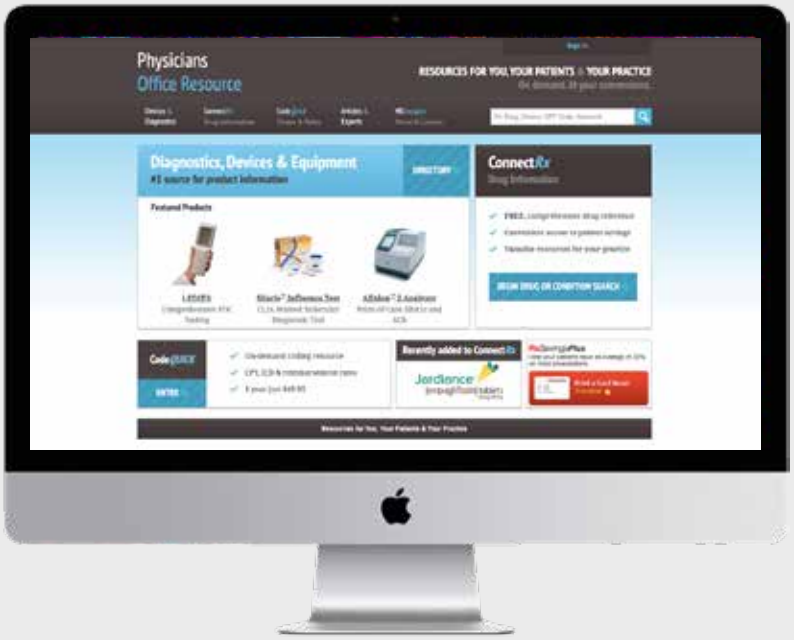
Questions for the Employing Physician

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10 WAYS PHYSICIANS CAN HELP

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*When compared to immunoassay products in market (refer to manufacturer instructions for use)

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Composite Comparator: Nasal and Nasopharyngeal Swabs



Influenza A - 96.4% (95% CI: 93.1% - 98.2%)
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Influenza A - 96.0% (95% CI: 94.4% - 97.2%)
Influenza B - 98.1% (95% CI: 96.9% - 98.8%)

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VACCINATION HESITATION

10 Ways Physicians Can Help Combat COVID-19 Vaccine Hesitancy

There are a variety of concerns and misunderstandings that lead to vaccine hesitancy. Not only should a healthcare practitioner be prepared to address the most common ones, but they should do their best to completely understand why a patient may be hesitant to receiving the vaccine and then provide the necessary resources for them to resolve their concern.

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PREPARING FOR YOUR INSPECTION: A LABORATORY CHECKLIST

—

The Clinical Laboratory Improvement Amendments (CLIA), passed by Congress in 1988, mandate that all test sites performing non-waived testing must undergo an inspection every two years. These inspections are designed to evaluate compliance with the quality standards set for all testing performed, to ensure the accuracy, reliability and timeliness of patient test results. All laboratories issued a CLIA certificate and all CLIA-exempt laboratories must comply with the applicable inspection requirements.

28

STRUCTURING YOUR STAFF MODEL: QUESTIONS FOR THE EMPLOYING PHYSICIAN

—

When physician employers recruit their practice staff, they're crafting an extension of themselves. Like a swiss watch or say, a Star Fleet command, each staff member contributes an invaluable service to the greater effectiveness of the practice, from answering phones, to coding procedures and to treating patients. Besides cultivating an efficient practice landscape, one which streamlines the divide between the administrative and clinical sides of the equation, these staff members also account for a significant portion of a practice's overhead.

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Broad test menu with over 20 assays to choose from including 14 that are now available as moderately complex.

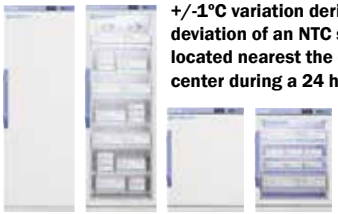
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+/-1°C variation derived from the maximum deviation of an NTC sensor in a 1 oz. vial located nearest the champer geometric center during a 24 hour test period

Refrigerators & Freezers From 23 to 49 Cu.ft.

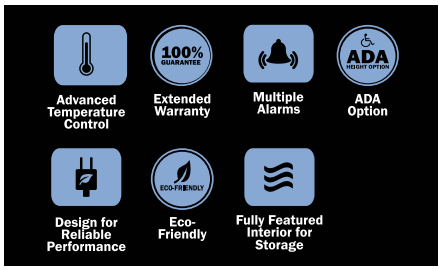


Refrigeration designed and purpose-built for pharmacy, medication, and vaccination applications to support meeting CDC/VFC vaccine storage guidelines

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Accucold	Capacity	Height	Width	Depth	Door	PRICE
ARS1PV	1 cu.ft.	21.5"	17.5"	19.5"	White	**815.00**
ARG1PV	1 cu.ft.	21.5"	17.5"	20"	Glass	**820.00**
ARS3PV	3 cu.ft.	33.75"	18.5"	19"	White	**884.00**
ARG3PV	3 cu.ft.	33.75"	18.5"	19.5"	Glass	**897.00**
ARS6PV	6 cu.ft.	32.5"	23.5"	24.5"	White	**996.00**
ARG6PV	6 cu.ft.	32.5"	23.5"	25"	Glass	**1,010.00**
ARS8PV	8 cu.ft.	50"	23.38"	24.5"	White	**1,218.00**
ARG8PV	8 cu.ft.	50"	23.38"	25"	Glass	**1,287.00**
ARS12PV	12 cu.ft.	61.75"	23.38"	24.5"	White	**1,690.00**
ARG12PV	12 cu.ft.	61.75"	23.38"	25"	Glass	**1,704.00**
ARS15PV	15 cu.ft.	72"	23.5"	24.5"	White	**1,866.00**
ARG15PV	15 cu.ft.	72"	23.5"	25"	Glass	**1,879.00**

models with data loggers are available

Pharma-Lab Refrigerators

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

Pharma-Lab Freezers

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

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Choosing the Right Sized Unit

Below are a few handy steps for determining the ideal Accucold refrigerator size for your clinic:

1 Estimate the maximum number of doses of publicly-provided vaccine and privately purchased vaccine that will be in your refrigerator.

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

Public Vaccine _____

Private Vaccine + _____

Total doses = _____

Multiply (max inventory) **x 1.25**

Maximum doses = _____

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

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

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19
Coronavirus
Vaccine
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Vaccination Hesitation:

10 WAYS PHYSICIANS CAN HELP

BY AARON MEDARIS, PUBLISHER, PHYSICIANS OFFICE RESOURCE

Vaccine hesitancy is nothing new. Even before unsubstantiated claims of autism, social media misinformation, and antivax websites, many people have struggled with vaccinations. In the smallpox outbreak of the 1800's the United Kingdom saw so much opposition that it finally had to require vaccination against the disease mandated by law. In the early 1900's the case of Jacobson v Massachusetts made its way the US Supreme Court. In the end the US Supreme Court supported the rights of states to pass laws mandating the smallpox vaccine. In 2019, before the pandemic even struck, the World Health Organization listed combating vaccine hesitancy as a top ten priority. Though vaccine hesitancy is nothing new, its effect on public health has never had a greater potential impact than on today's world. In just over one year of battling the pandemic on US soil, there have been over 525,000 COVID-19 related deaths. We now have three FDA authorized COVID-19 vaccines that have fully vaccinated over 30,000,000 people. Recent data suggests that about 80 to 85% of Americans would need to be vaccinated to achieve herd immunity against COVID-19. Given that the population of the United States is about 328,000,000, we still need to vaccinate roughly 70 to 75% of the population. Which brings up the question, how much will vaccine hesitancy play a role in the US gaining heard immunity? If recent surveys are correct, it could have a major impact. According to national poll sponsored by the University of Michigan in the fall of 2020, just 58% of adults aged 50 to 80 said they'd get vaccinated against COVID-19. If in the end those numbers prove to be accurate, we will have fallen well short of required vaccinated population to achieve heard immunity. We need to be prepared to help the population and their vaccination concerns.

Five Common Concerns or misunderstandings with the COVID-19 Vaccine leading to vaccination hesitancy:

1. How quickly the vaccine was developed
2. Side effects of the vaccine
3. Only the vulnerable need to be vaccinated
4. Don't know how long the vaccine will last
5. How the vaccine work against COVID mutations

There are a variety of concerns and misunderstandings that lead to vaccine hesitancy. Not only should a healthcare practitioner be prepared to address the above, but they should do their best to completely understand why a patient may be hesitant to receiving the vaccine and then provide the necessary resources for them to resolve their concern.

Here are 10 ways that physicians and other healthcare practitioners can help combat COVID-19 vaccine hesitancy:

1. Ask Why the Patient is Hesitant

Whether their concern is one of the five listed above or something completely different, it is essential that a physician understand a patient's concerns. In the end every patient must make the decision for themselves to be vaccinated, but you will want to do all that you can to understand where the patient is coming from and what their concerns are. Sometimes people's concerns are like an iceberg with only a small portion visible above the surface. Concerns like this can be difficult to resolve that is why it is essential to ask questions and listen intently to the patient's response. Jumping to conclusions rather than listening to the patient can damage trust and cause further vaccination hesitancy.

2. Listen

Asking questions will only get you so far when helping others with their concerns. When you listen carefully to others, you understand them better. When they know that their responses are important to you, they will open up more. One common habit many of us have is when someone is speaking, we often think about what we will say in response. This practice often leads us to only hear part of their message. If we listen with intent, we will better grasp what they are saying which will allow us to provide a more appropriate response. When you feel like you understand what is being said verify that by using such statements and questions as, "So what you're saying is_____. Is that right?" or If I understand correctly, you're concerned with _____. Is that correct?"

3. Share Empathy and Provide Emotional Support

Empathy can be a difficult attribute to attain. However, proper

development of cognitive, emotional, and compassionate empathies will allow you better understand your patient and share in their feelings. Empathy doesn't mean you have to agree with their concerns, it means that you understand them and understand the impact those concerns can have on someone's mental and emotional state. Reaching that level of understanding can only be obtained through a sincere desire to help and in the case of a physician, a sincere desire to heal. Vaccination concerns often arise because of distrust, when a patient see's and recognizes that you have empathy for them regardless of where their concerns are coming from, they will come to trust you more.

4. Acknowledge Uncertain Risk

We face risk every day and take precautions every day to minimize risk. We take risks every time we get into a vehicle and travel 70 miles per hour on the interstate. We minimize the risks involved with the activity by wearing our seatbelt, staying attentive, and obeying traffic laws. People respond very differently to new risks. When I was a teenager first learning to drive, diving on the interstate for the first time was terrifying and probably even more terrifying for my parents who were teaching me how to drive. However, with practice and appropriate skill, I no longer look at that task as terrifying. In fact, I look at it as a necessity to go about my everyday life. Some people may look at getting the COVID-19 vaccine as terrifying because to them it's new and with that new experience comes unknowns. However, getting vaccinated is like putting on a seatbelt and following traffic laws that will help you go about your everyday life. The real risk would be choosing not to be vaccinated or in a sense not wearing your seatbelt and not obeying traffic laws with the hope of arriving safely at your destination.

5. Discuss Known Risks

Be upfront. Make sure that patients understand what side effects are possible with getting vaccinated, such as fever, muscle aches, flu like symptoms. Also discuss the rare risk of allergic reactions (2.5 anaphylaxis cases per million Moderna COVID-19 vaccine doses administered) and what is being done to respond to those situations.

6. Provide Information

Proper information can be a powerful tool to the vaccine hesitant. There are many who fall into the undecided category when it comes to getting the COVID-19 vaccine. A large reason why they fall into that category is because they haven't had a chance to educate themselves on the vaccine. They've heard snippets on the news and hearsay from friends and family, but rarely have they received proper professional information regarding the COVID-19 vaccine. Referrals to appropriate websites such as the following can provide answers to the questions that are standing in the way of their decision to vaccinate:

Questions and Answers about the COVID-19 Vaccine

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html

https://www.health.harvard.edu/coronavirus-and-covid-19/covid-19-vaccines

Myths and Facts about the COVID-19 Vaccine
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html

https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/coronavirus-vaccine/art-20484859

7. Partner with Communities

Many who are vaccine hesitant are dealing with familial or societal situations that are skeptical of the COVID-19 vaccine. It's important as a physician, healthcare provider, or public health administrator to partner with those that have longstanding relationships with various communities to provide appropriate and accurate information regarding the COVID-19 vaccines.

8. Get the Vaccine Yourself and Tell Others About Your Experience

You are your patient's expert on all things health. Your word, advice, and treatment mean a lot to them. In a pandemic, we're all facing the same disease and we luckily for us all have the same defensive measures. Get the vaccine yourself and tell others about your experience. Share the good, share the side effects, share why you chose to get vaccinated. Your words and personal experience can be the motivating factor your patient needs to get vaccinated.

9. Tell Your Patients They Need to Get Vaccinated

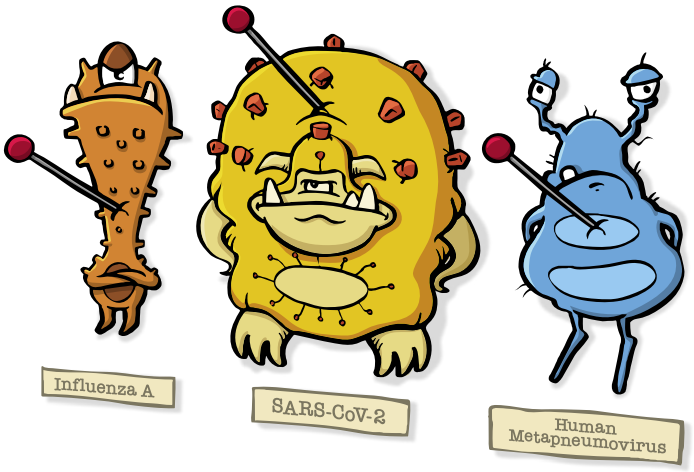
Obviously, there are cases where a patient should not be vaccinated and you should be aware of those. But in most cases, vaccination is a must. Tell your patients to get vaccinated. Plain and simple. You tell patients every day to stop smoking, eat better, lose weight, and take their prescribed medicines. Telling your patients to get vaccinated should not be any different.

10. People Have a Natural Desire to Protect Others

We've seen the statistics, there is a portion of the population that is extremely susceptible to the devastating effects of COVID-19. Many of those are our loved ones. What if we could do something that could provide those people at risk many more years of quality life? Well, we can. We can get vaccinated. Tap into that desire people have to protect others. Their selfless act of being vaccinated could mean life or death for someone else.

There will always be those with concerns regarding any type of vaccination. I'm ok with that. Those with concerns are concerned about their health and the health of those they love. But I also don't think we should look at those with vaccine hesitancy as a lost cause. I believe with the proper approach many of their concerns can be resolved and ultimately lead to proper vaccination.

It's been a long year of battle against this pandemic. We are so fortunate to have three approved vaccines that could eventually bring it to an end. We offer our sincerest gratitude to you physicians, healthcare providers, and scientists. I can't imagine what this past year would have been like without you on the front lines.



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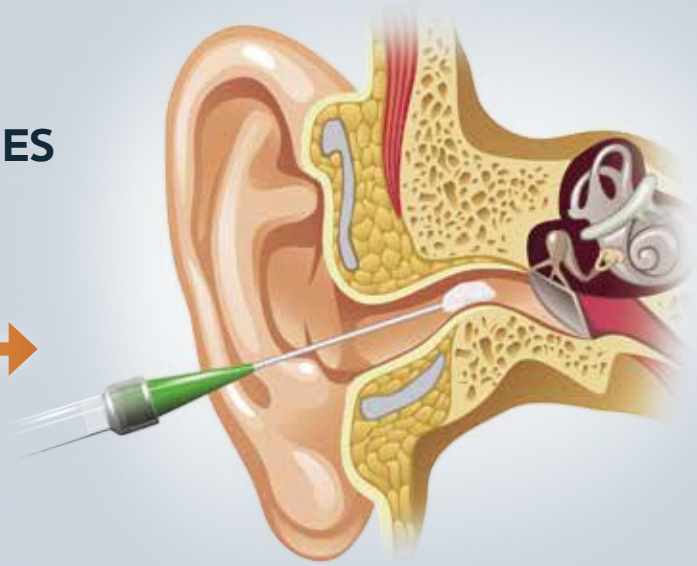
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THERMOSENSITIVE PROPERTIES



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



For more information on OTIPRIO, please contact your local ALK representative or call 1-800-325-7354.

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®

OTIPRIO is being marketed by ALK-Abelló, Inc. and Otonomy, Inc.

OTIPRIO is a registered trademark of Otonomy, Inc.
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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.

Distributed by: Otonomy, Inc. San Diego, CA 92121
www.otiprio.com

OTIPRIO® is a registered trademark of Otonomy.

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

ALK OTONOMY®

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PREPARING FOR YOUR INSPECTION: A LABORATORY CHECKLIST

BY IRWIN Z. ROTHENBERG, MBA, MS, CLS (ASCP), TECHNICAL WRITER /QUALITY ADVISOR

Introduction

The Clinical Laboratory Improvement Amendments (CLIA), passed by Congress in 1988, mandate that all test sites performing non-waived testing must undergo an inspection every two years. These inspections are designed to evaluate compliance with the quality standards set for all testing performed, to ensure the accuracy, reliability and timeliness of patient test results. All laboratories issued a CLIA certificate and all CLIA-exempt laboratories must comply with the applicable inspection requirements.

The laboratory will either be inspected by CMS/CLIA (generally by state inspectors) or by an accrediting organization (AO) that has been granted deeming authority by CMS. There are currently seven CMS-approved accreditation organizations: AABB, American Association for Laboratory Accreditation (A2LA), American Osteopathic Association (AOA), American Society of Histocompatibility and Immunogenetics (ASHI), COLA, CAP, and The Joint Commission (TJC).

Regardless of the agency, all inspections focus on essentially the same areas. While being "ready" can't guarantee a stress-free inspection, it will indicate the laboratory has already adopted the culture of quality patient care, and that it can continue to improve from there.

CLIA follows a biennial inspection schedule. Some private Accrediting Organizations follow a more general 18-24 month schedule, so it would be prudent for laboratories to be additionally vigilant during these time frames.

Inspections may or may not be announced in advance, depending on the Accrediting Organization. It is also important to be aware of how notification is provided: on-line, email, postal mail, telephone or fax. Make sure that the notifications go to the proper individuals. It should be noted that if there has been a complaint against a laboratory, the inspection/survey may be unannounced.

Preparing For an Inspection: General Guidelines For Operating a Compliant Laboratory

- Be familiar with the regulatory requirements for your laboratory as determined by your inspection agency, reflecting the type of CLIA certificate required; the complexity of your test menu; the specialties represented in your test menu; the type(s) of instrumentation, and whether outside reference work is performed by your laboratory.

- Ensure that all positions in the laboratory are filled by qualified personnel; have complete documentation of education, experience, training, and competency assessments; all job descriptions current.

- Establish and maintain written policy, process, and procedure manuals. These must include procedures for all phases of testing performed by the laboratory; define quality control by the frequency, type and number used; include corrective action protocols; list critical values when appropriate, with follow up actions; and specimen acceptability requirements. All manuals must include the Laboratory Director's signed and dated review and approval.

- Be enrolled and participate in a proficiency testing program appropriate for your test menu and specialties.

- Instrument calibration, maintenance, and quality control are performed as required.

- Instrument performance specifications have been verified.

- Verify the security of your Laboratory Information System (LIS); as well as the accuracy of data entered and stored.

- Incorporate quality assessment into the daily routine of

the laboratory. This includes assessing the quality through out the testing process; taking corrective actions when needed; and following up on the effectiveness of corrective actions.

- Ensure that all required documentation is maintained in accordance with CLIA requirements.

The Day of the Inspection

The inspector will need documentation of all laboratory functions described below, including patient charts when requested, for the past two-years, or from the date of the last AO / CMS CLIA inspection. These records should be collected prior to the inspection and placed in a room with an electrical outlet. The list below is not all-inclusive, but represents the basic items required. Depending on individual circumstances, the surveyor may request additional records.

- Copy of current CLIA Certificate for surveyor to review and retain if required.
- Personnel files for each laboratory employee (including physicians) performing non-waived testing. Files must include:

  Proof of education according to CLIA '88 requirements. The following documents are acceptable: High school diploma, GED, Transcripts (must have date graduated), college degrees (AS, BS, MS, and PhD), and MD/DO Licenses.

  1. MT & MLTS must have either copies or tran scripts of the advanced degrees (AS, BS, MS). ASCP or other professional society cards or certificates cannot be accepted as the only proof of qualification.
  2. Medical Assistants, LPNs, and RNs must have either high school diplomas or advanced degrees available. Licenses cannot be accepted as the only proof of qualification.
  3. Those employees with only foreign educational documents must have them evaluated for equivalency to a US high school diploma, or college degree by an officially recognized education evaluation organization.
  4. In those states that license laboratory personnel, a copy of a current state license can be accepted. It is advisable to have copies of the corresponding educational degree as well.

- Written performance evaluations and/or technical skill competencies. New employees must be evaluated at six months and also one year after their hire; other employees must be evaluated yearly.
- Training documents for all new employees or some proof of their previous experience, such as resumes and prior instrument training.
- Job descriptions for all employees.
- Policy & Procedure Manual(s) including all Instrument Operator's Manuals.
- Current package inserts for all kit tests and reagents (including all waived methods).
- Package inserts for all controls and calibration materials used during the survey period.
- Proficiency testing (PT) records including instrument tapes, test report forms, attestation statements, graded results, and corrective actions taken for all unsatisfactory scores.
- Instrument/equipment/pipette calibration, maintenance, and function check records for current and discontinued instruments used during the survey period.
- Temperature and humidity records.
- All quality control (QC) records, graphical representations, charts, and any other documentary logs involved. IQCP studies
- Test requisitions and report forms used for all laboratory testing. The inspector may ask to review several patient charts.
- Incident Management Plan and any reports.
- Quality Assessment (QA) Plan and documentation of implementation - QA reviews.

Once the inspection has been completed and an exit conference or interview has occurred with the inspector, the laboratory director should share all findings with the laboratory personnel. Sharing the information in a timely fashion will allow the laboratory the opportunity to begin addressing deficiencies immediately and prepare for subsequent inspections.

Conclusion

Preparing for a laboratory inspection brings anxiety and stress above and beyond those of a normal work day. Optimizing quality laboratory medicine and quality patient care is the goal for all clinical laboratories, but being prepared and doing well on your laboratory inspection should also bring a special sense of satisfaction.

Endnotes

Preparing For an Initial Laboratory Survey. Oregon Health Authority. http://public.health.oregon.gov/LaboratoryServices/ClinicalLaboratoryRegulation/Documents/init.pdf

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

Point-of-Care Testing

Physician Office Laboratories

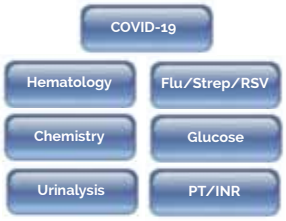
Urgent Care & Emergency Centers

Pain Management Laboratories

Cost-effective, Easy to Use Lab Data Management and Compliance Software Solutions
POC to High Complexity Testing

- Automatically manage patient lab test orders to completed results
- Connect to EHR - post results to patient chart
- Document lab compliance requirements - QC and patient results all in one place

Instruments of Choice



Medicus POC LIS

EHR



9122

Medicus
LABORATORY INFORMATION SYSTEMS

Link Your Lab
medicuslis.com

For more information, please call 888.643.8081 or email sales@medicuslis.com



IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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

ADVERSE REACTIONS

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

Patients should be counseled on the following:

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

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

For Women Who Are BEYOND HORMONES™

A non-hormonal prescription contraceptive vaginal gel that's used in the moment

For the women in your practice who...

- Prefer non-hormonal contraception because of unwanted side effects experienced with hormones
- Currently use condoms or withdrawal method
- Want an easily reversible method
- Are likely to research contraceptive options and prefer methods that fit their healthy lifestyles

How to prescribe Phexxi®

PHEXXI® VAGINAL GEL (5 g per applicator)

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

Rx

Dispense: # 12 applicators

NDC: 69751-100-12

Refill: 11

Discover all Phexxi® has to offer in an immersive experience

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

INDICATIONS AND USAGE

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

LIMITATIONS OF USE

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

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

EVOFEM BIOSCIENCES®

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Trademarks, registered or otherwise, are the property of their respective owner(s).
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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

Phexxi is a registered trademark of Evofem Biosciences, Inc.

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U.S. Patent 6,706,276

REFDOC-001013

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.

EVOFEM BIOSCIENCES®



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

From Carolina Liquid Chemistries

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

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9126

CRYOLAB® MEDICAL

From CryoConcepts

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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Enter Number **9126** in the Search Area

HISTOFREEZER® FLEX

From CryoConcepts

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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9127





9128

CRYOCLEAR®

From CryoConcepts

This is a new pen-like cryo devices that dispenses carbon dioxide which is perfect for superficial lesions such as sun spots, age spots, and shin tags. CryoClear® has enough gas to treat between 20 and 30 lesions depending on the size and type.

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HELPING YOU HIT THE MARK IN FLU TESTING

From Acucy®

The Acucy® Influenza A&B Test is for the rapid, qualitative detection of influenza A and B viral nucleoprotein antigens from both nasal and nasopharyngeal swabs. Utilizing the Acucy® Reader in either the point-of-care or laboratory setting, workflow flexibility is achieved with both Read Now and Walk Away features. The combination provides clinicians with standardized and definitive result interpretation.

—

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Enter Number **9129** in the Search Area

CLIA-WAIVED BIOFIRE® FILMARRAY® RESPIRATORY PANEL (RP) EZ

From BioFire

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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OSOM ULTRA PLUS FLU A&B TEST

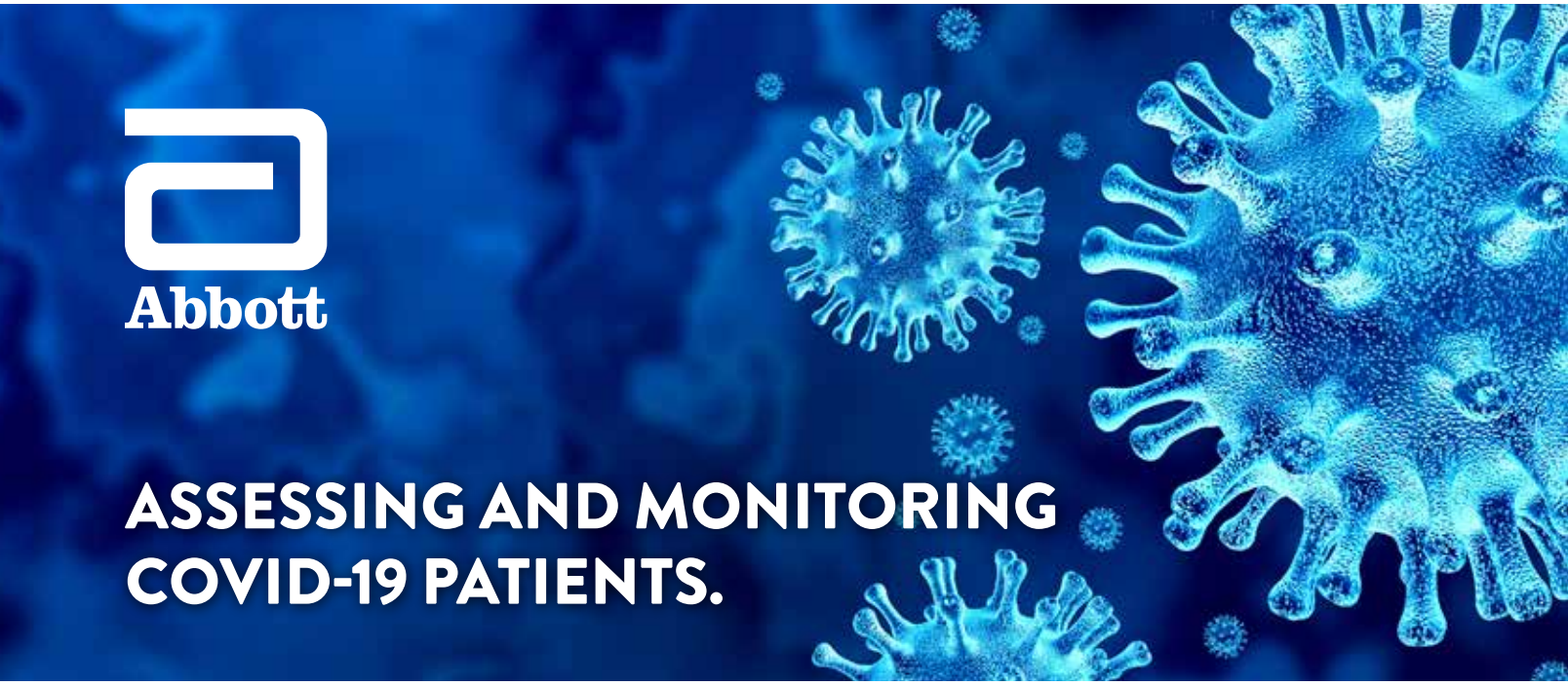
From Sekisui

Stronger Clinical Performance Takes Lateral Flow Testing To The Next Level. Providing superior rapid results at the point-of-care. Fast, easy, cost effective so you can test and treat in one visit.

- High Performance- Equivalent or exceeding the performance of reader devices, without the need for an instrument
- Results in 10 minutes
- OSOM® Custom Care- Exceptional Support/Training by licensed medical technologists and experienced healthcare professionals
- Made in the USA

—

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Enter Number **9131** in the Search Area



Abbott

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]



piccolo xpress chemistry analyzer

For *in vitro* diagnostic use only.

The Piccolo Xpress does not directly diagnose COVID-19.

ON-SITE TESTING MADE EASY: PICCOLO XPRESS.®

The Piccolo Xpress portable diagnostic analyzer offers a full complement of blood chemistry tests, including CLIA-waived tests.

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



Comprehensive Metabolic Panel
Na+, K+, CI-, tCO_2, Ca, BUN, Crea, Glu, ALB, ALP, ALT, AST, TP, tBIL, eGFR*



MetLyte 8
Na+, K+, Cl-, tCO_2, BUN, Crea, Glu, CK, eGFR*



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

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STRUCTURING YOUR STAFF MODEL:

QUESTIONS FOR THE EMPLOYING PHYSICIAN

BY DYLAN CHADWICK

When physician employers recruit their practice staff, they're crafting an extension of themselves. Like a swiss watch or say, a Star Fleet command, each staff member contributes an invaluable service to the greater effectiveness of the practice, from answering phones, to coding procedures and to treating patients. Besides cultivating an efficient practice landscape, one which streamlines the divide between the administrative and clinical sides of the equation, these staff members also account for a significant portion of a practice's overhead.

Decisions of which staff to hire, how many members and how to compensate them, can be a daunting task for any physician. The ultimate goal for most physicians when it comes to employing, according to Medscape's first ever Clinical Office Staff Salary Report, is to find those who can raise their own bottom line by reducing costs and delivering billable services.

Staffing Analysis

The strongest staffing model for one physician won't necessarily be the best for another. Says Kim Gooden, a practice administrator at Dermatology Consultants, a practice with three locations in the Atlanta metropolitan area, "Physicians are happier when they're able to utilize their staff in a way that's more efficient for them. She currently manages seven physicians, five physician assistants and 79 supporting staff (How to Conduct a Staffing Analysis).

With a changing medical landscape, one in which technology permeates deeper into the fabric of private-practice medicine, many physicians have found themselves re-thinking the personnel that they're hiring. To illustrate, imagine a practice that implements an EHR. This practice may need to hire more medical assistants to act as scribes or data-input specialists, trained in the system's program. Besides medical technology, healthcare reform and fluctuating reimbursement rates play big into how an employing physician chooses to structure their staff.

For an employing physician looking to restructure their practice, a staffing analysis can help physicians get an accurate count of their practice and its individual strengths and weaknesses.

The General Overview

The first real question that any staffing analysis should answer is whether or not a practice has the "right" amount of staff. Besides workflow concerns, it's also a critical component in determining reimbursements. A practice with too few staff may struggle with productivity and wait times, whereas a practice



that has too many staff may become too expensive and create insurmountable overhead challenges.

Physicians can consult various benchmark reports within the industry, reports that survey staffing numbers of practices with similar specialties and sizes. However, these are just benchmarks and if a particular practice differs significantly from any national averages, it shouldn't send any physicians into a panic. Every medical practice functions differently, and is a product of several other nuanced, non-clinical factors like geography, demographic and income bracket. As a medical practice is highly individual and unique, so to should a staff structure be.

Who's Doing What?

Another purpose of a staffing analysis is to accurately determine whether each staff member has been tasked with the most correct and efficient responsibilities. Westgate's article suggests using a measuring stick like to determine these tasks. As an example, analyzers can choose a certain task (like "answering phones") and write it on a paper, tape it to the wall in a staffing area and ask staff involved to write down each role and the responsibility associated with it. These kinds of exercises may lead to a re-configuring of staffer responsibilities, especially if it reveals that staff members are spending too much time on tasks which take them away from their "core" responsibilities and prevent them from their best productivity. Good questions to ask in this regard may be, "how can my practice reduce the number of steps involved in the workflow?" or "how can I utilize technology to improve the process?"

Technology

At this point, there's not really much debate as to whether or not technology can improve workflow, it's just a question of integration. That's also what makes it a relevant component to consider when conducting a staffing analysis. Things to take into account are the fact that when a practice acquires new technology, it likely forecasts some time in order to restructure responsibilities to adequately accommodate it.

Performance Evaluation

In the analysis, the "Staff performance" category can be difficult to empirically assess. Experts in the field suggest shooting for 75-85% of a practice's staff members to be somewhere in a "top performers" category, with a solid mentoring or coaching system put in place for any who struggle.

Analysts may also find that calculating a measurement of various staff member workload ranges can assist in the assessment.

"Overall, physician pay scales reflect the state of the market, changing landscape conditions (like healthcare reform) and the value an individualized practice puts on an individual service."

Industry benchmarks can help, but a solid rule of thumb is to determine how long it takes various staff members to complete their tasks and how much work can be completed by a single staff member in a workday. However, this is nitty-gritty evaluation components that get deep into "nuts and bolts" territory that can be rather time-intensive. Some practices may have phone systems that record call statistics and can give figures such as the average call length. For those who don't, informed estimates are just as effective.

Payment

Once the staffing analysis is complete, the ideal number of staff has been determined and they're tasked with the correct responsibilities, employing physicians can consider payment models for their staff.

Medscape's official report Physician Compensation Report surveys United States doctors from a wide range of specialties regarding their own salaries and the compensation packages they offer their various staff members.

Monetary Benchmarks

According to the study and report, non-clinician employees earn less than their clinical staff peers across the board. Roughly ⅔ (64 per cent) of surveyed physicians report paying their front desk staff less than $30,000 annually. However, there are those who acknowledge the reality that front desk personnel have a tremendous impact in patient satisfaction by setting the tone of the patient's office visit and by facilitate practice efficiency by scheduling appointments, fielding phone calls and other billing and coding duties, and they'll pay them accordingly. 35 percent pay their front desk personnel between $30-60,000 annually and a smaller portion (1 percent) pay even more than this.

Medical records clerks earn less, and 31 percent of surveyed practices employ them. 72 percent of these participating physicians report paying record clerks less than $30,000. Medical billers statistically (60 percent) earn more, somewhere between $30,000-60,000.

Rewarding Revenue Creators

In consulting national statistics, employing physicians reward their staff who can generate more revenue for the practice. These sorts of staff work in roles like nurse practitioners and physicians assistants because they allow a practice to accommodate more patients at one time. Healthcare reform is forcing many states to expand the scope of services that Nurse Practitioners and Physician's Assistants hold. They can economically benefit a practice because they alleviate many of a physician's duties so that they can more specially focus on areas that have the highest reimbursements. They also provide services which are billable under Medicare and enable primary care physicians to compete with retail clinics that are developing around the country. According to the report, 55 percent report paying their nurse practitioners more than $80,000 annually, and 16 percent pay more than $100,000. Physicians assistants see a similar payment curve with 57 percent of them earning upwards of $80,000 and 19 percent earning more than $100,000.

Occupational Benefits

Monetary compensation isn't all an employing physician must consider, as benefits packages are equally important to staff morale and job competition. According to the survey, most private practice physicians offer staff paid vacation and sick time (80 percent) and paid for health insurance (68 percent). Roughly half (46 percent) offered a retirement plan with a match and a smaller portion (22 percent) offer one without a match.

By and large, the huge benefits packages offered by corporate America aren't as common in healthcare practices. Only about ⅓ (36 percent) provide dental plans for staff members and even fewer offer healthcare savings accounts (26 percent), vision insurance (23 percent), short term disability (22 percent), life insurance (19 percent) or long-term disability (16 percent) policies.

The Bottom Line

Overall, physician pay scales reflect the state of the market, changing landscape conditions (like healthcare reform) and the value an individualized practice puts on an individual service. While each practice has different needs, strengths and deficits, a thorough staffing analysis and an informed consultation of industry benchmarks and reports can help employing physicians make the most efficient and economical decisions for their staffing model.

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MAR-115 (Rev 1)

For adults with intermediate- or high-risk myelofibrosis (MF)[1]

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JAKAFI® (RUXOLITINIB) AT DIAGNOSIS

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Ruxolitinib (Jakafi) is a Category 2A* treatment option for both symptomatic lower-risk† and higher-risk MF – in patients with platelets ≥50 x 10^9/L.[2‡]

*Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.[2]

†Lower-risk MF is defined as low or intermediate-1 risk based on DIPSS, DIPSS-Plus, and MYSEC-PM, low or intermediate risk based on MIPSS-70 (threshold of ≤3 prognostic variable points), and very low, low, or intermediate risk based on MIPSS-70+ (version 2.0; threshold of ≤3 prognostic variable points).[2]

‡In patients who are not transplant candidates.

SIGNIFICANTLY MORE PATIENTS RECEIVING JAKAFI EXPERIENCED IMPROVEMENT IN MF-RELATED SPLENOMEGALY[1,3,5]

COMFORT-I PRIMARY ENDPOINT[1,3‡]

42% of patients receiving **Jakafi** achieved a ≥35% reduction in spleen volume at week 24 **vs** **0.7%** of patients receiving **placebo** ($P < 0.0001$)

- 4.4 years median duration of spleen response among primary responders (n = 65)[4§]

COMFORT-II PRIMARY ENDPOINT[1,5‖]

29% of patients receiving **Jakafi** achieved a ≥35% reduction in spleen volume at week 48 **vs** **0%** of patients receiving **best available therapy**[¶] ($P < 0.0001$)

Indications and Usage

Jakafi is indicated for treatment of intermediate or high-risk myelofibrosis (MF), including primary MF, post–polycythemia vera MF and post–essential thrombocythemia MF in adults.

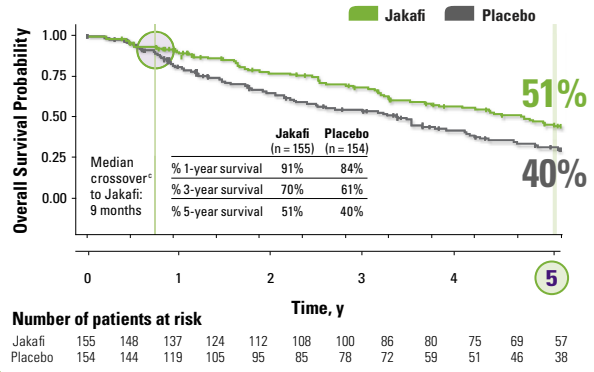
Important Safety Information

- Treatment with Jakafi® (ruxolitinib) can cause thrombocytopenia, anemia and neutropenia, which are each dose-related effects. Perform a pre-treatment complete blood count (CBC) and monitor CBCs every 2 to 4 weeks until doses are stabilized, and then as clinically indicated
- Manage thrombocytopenia by reducing the dose or temporarily interrupting Jakafi. Platelet transfusions may be necessary
- Patients developing anemia may require blood transfusions and/or dose modifications of Jakafi
- Severe neutropenia (ANC <0.5 × 10^9/L) was generally reversible by withholding Jakafi until recovery
- Serious bacterial, mycobacterial, fungal and viral infections have occurred. Delay starting Jakafi until active serious infections have resolved. Observe patients receiving Jakafi for signs and symptoms of infection and manage promptly. Use active surveillance and prophylactic antibiotics according to clinical guidelines
- Tuberculosis (TB) infection has been reported. Observe patients taking Jakafi for signs and symptoms of active TB and manage promptly. Prior to initiating Jakafi, evaluate patients for TB risk factors and test those at higher risk for latent infection. Consult a physician with expertise in the treatment of TB before starting Jakafi in patients with evidence of active or latent TB. Continuation of Jakafi during treatment of active TB should be based on the overall risk-benefit determination
- Progressive multifocal leukoencephalopathy (PML) has occurred with Jakafi treatment. If PML is suspected, stop Jakafi and evaluate
- Advise patients about early signs and symptoms of herpes zoster and to seek early treatment
- Increases in hepatitis B viral load with or without associated elevations in alanine aminotransferase and aspartate aminotransferase have been reported in patients with chronic hepatitis B virus (HBV) infections. Monitor and treat patients with chronic HBV infection according to clinical guidelines
- When discontinuing Jakafi, myeloproliferative neoplasm-related symptoms may return within one week. After discontinuation, some patients with myelofibrosis have experienced fever, respiratory distress, hypotension, DIC, or multi-organ failure. If any of these occur after discontinuation or while tapering Jakafi, evaluate and treat any intercurrent illness and consider restarting or increasing the dose of Jakafi. Instruct patients not to interrupt

JAKAFI 3-YEAR AND 5-YEAR OVERALL SURVIVAL ANALYSES

Jakafi® ruxolitinib (tablets)

Overall Survival Kaplan-Meier Curves by Treatment Group in COMFORT-I[1,4,6,a,b]



Number of patients at risk

Jakafi	155	148	137	124	112	108	100	86	80	75	69	57
Placebo	154	144	119	105	95	85	78	72	59	51	46	38

Adapted with permission from the *Journal of Hematology & Oncology*.[6]

COMFORT-I: 5-YEAR ANALYSIS OF JAKAFI AND PLACEBO[6]

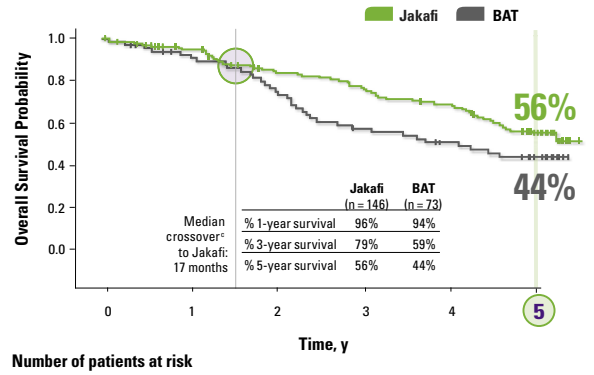
- At 3 years, survival probability was 70% for patients originally randomized to Jakafi and 61% for those originally randomized to placebo[1]
- Overall survival was a prespecified secondary endpoint in COMFORT-I[1]

JAKAFI 5-YEAR OVERALL SURVIVAL PROBABILITY WAS 51%[4]

- All patients in the placebo group either crossed over to Jakafi at a median of 9 months or discontinued[1]

[a] The 5-year overall survival analysis is not included in the Full Prescribing Information for Jakafi. Although the 3-year overall survival analysis is presented in the Full Prescribing Information, *P* values and hazard ratios are omitted from the overall survival Kaplan-Meier curves.[4]
[b] COMFORT-I was not designed to compare survival probabilities between Jakafi and placebo at 3 or 5 years.[4]
[c] Patients randomized to placebo were eligible to cross over to receive Jakafi because of progression-driven events or at the physician's discretion; however, these patients continued to be grouped within their original randomized assignment for analysis purposes.[4]
[‡] COMFORT-I (COntrolled MyeloFibrosis study with ORal JAK inhibitor Treatment-I) was a randomized, double-blind, placebo-controlled phase 3 study with 309 patients with intermediate-2–risk or high-risk MF. The primary endpoint was the proportion of patients achieving a ≥35% reduction in spleen volume from baseline to week 24 as measured by CT or MRI.[1,3]
[§] Duration of spleen response was defined as the interval between the first spleen response measurement that was a ≥35% reduction from baseline and the date of the first measurement that was no longer a ≥35% reduction from baseline that was also a >25% increase from nadir.[4]

Overall Survival Kaplan-Meier Curves by Treatment Group in COMFORT-II[1,7,a,b]



Number of patients at risk

Jakafi	146	130	109	100	88	61
BAT	73	58	48	35	30	22

Adapted with permission from *Leukemia*.[7]

COMFORT-II: 5-YEAR ANALYSIS OF JAKAFI AND BEST AVAILABLE THERAPY[7]

- At 3 years, survival probability was 79% for patients originally randomized to Jakafi and 59% for those originally randomized to best available therapy[1]
- Overall survival was a prespecified secondary endpoint in COMFORT-II[1]

JAKAFI 5-YEAR OVERALL SURVIVAL PROBABILITY WAS 56%[7]

- All patients in the best available therapy group either crossed over to Jakafi at a median of 17 months or discontinued[1]

BAT, best available therapy.

[a] The 5-year overall survival analysis is not included in the Full Prescribing Information for Jakafi. Although the 3-year overall survival analysis is presented in the Full Prescribing Information, *P* values and hazard ratios are omitted from the overall survival Kaplan-Meier curves.[4]
[b] COMFORT-II was not designed to compare survival probabilities between Jakafi and best available therapy at 3 or 5 years.[4]
[c] Patients randomized to best available therapy were eligible to cross over to receive Jakafi because of progression-driven events or at the physician's discretion; however, these patients continued to be grouped within their original randomized assignment for analysis purposes.[4]
[‖] COMFORT-II (COntrolled MyeloFibrosis study with ORal JAK inhibitor Treatment-II) was a randomized, open-label phase 3 study with 219 patients with intermediate-2–risk or high-risk MF. The primary endpoint was the proportion of patients achieving a ≥35% reduction in spleen volume from baseline at week 48 as measured by CT or MRI.[1,5]
[¶] Best available therapy in COMFORT-II included hydroxyurea (46.6%) and glucocorticoids (16.4%), as well as no medication, anagrelide, epoetin alfa, thalidomide, lenalidomide, mercaptopurine, thioguanine, danazol, peginterferon alfa-2a, interferon-α, melphalan, acetylsalicylic acid, cytarabine, and colchicine.[4]

For more data on long-term results with Jakafi, visit JakafiResults.com

or discontinue Jakafi without consulting their physician. When discontinuing or interrupting Jakafi for reasons other than thrombocytopenia or neutropenia, consider gradual tapering rather than abrupt discontinuation

- Non-melanoma skin cancers including basal cell, squamous cell, and Merkel cell carcinoma have occurred. Perform periodic skin examinations
- Treatment with Jakafi has been associated with increases in total cholesterol, low-density lipoprotein cholesterol, and triglycerides. Assess lipid parameters 8-12 weeks after initiating Jakafi. Monitor and treat according to clinical guidelines for the management of hyperlipidemia
- In myelofibrosis and polycythemia vera, the most common nonhematologic adverse reactions (incidence ≥15%) were bruising, dizziness, headache, and diarrhea. In acute graft-versus-host disease, the most common nonhematologic adverse reactions (incidence >50%) were infections and edema
- Dose modifications may be required when administering Jakafi with strong CYP3A4 inhibitors or fluconazole or in patients with renal or hepatic impairment. Patients should be closely monitored and the dose titrated based on safety and efficacy
- Use of Jakafi during pregnancy is not recommended and should only be used if the potential benefit justifies the potential risk to the fetus. Women taking Jakafi should not breastfeed during treatment and for 2 weeks after the final dose

Please see Brief Summary of Full Prescribing Information for Jakafi on the following pages.

To learn more about Jakafi, visit **HCP.Jakafi.com**.

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Incyte

Jakafi®
ruxolitinib (tablets)

BRIEF SUMMARY: For Full Prescribing Information, see package insert.

INDICATIONS AND USAGE Myelofibrosis Jakafi is indicated for treatment of intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF in adults. **Polycythemia Vera** Jakafi is indicated for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea. **Acute Graft-Versus-Host Disease** Jakafi is indicated for treatment of steroid-refractory acute graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older.

CONTRAINDICATIONS None.

WARNINGS AND PRECAUTIONS Thrombocytopenia, Anemia and Neutropenia Treatment with Jakafi can cause thrombocytopenia, anemia and neutropenia. [*see Dosage and Administration (2.1) in Full Prescribing Information*]. Manage thrombocytopenia by reducing the dose or temporarily interrupting Jakafi. Platelet transfusions may be necessary [*see Dosage and Administration (2), and Adverse Reactions (6.1) in Full Prescribing Information*]. Patients developing anemia may require blood transfusions and/or dose modifications of Jakafi. Severe neutropenia (ANC less than 0.5×10^9/L) was generally reversible by withholding Jakafi until recovery [*see Adverse Reactions (6.1) in Full Prescribing Information*]. Perform a pre-treatment complete blood count (CBC) and monitor CBCs every 2 to 4 weeks until doses are stabilized, and then as clinically indicated [*see Dosage and Administration (2), and Adverse Reactions (6.1) in Full Prescribing Information*]. **Risk of Infection** Serious bacterial, mycobacterial, fungal and viral infections have occurred. Delay starting therapy with Jakafi until active serious infections have resolved. Observe patients receiving Jakafi for signs and symptoms of infection and manage promptly. Use active surveillance and prophylactic antibiotics according to clinical guidelines. *Tuberculosis* Tuberculosis infection has been reported in patients receiving Jakafi. Observe patients receiving Jakafi for signs and symptoms of active tuberculosis and manage promptly. Prior to initiating Jakafi, patients should be evaluated for tuberculosis risk factors, and those at higher risk should be tested for latent infection. Risk factors include, but are not limited to, prior residence in or travel to countries with a high prevalence of tuberculosis, close contact with a person with active tuberculosis, and a history of active or latent tuberculosis where an adequate course of treatment cannot be confirmed. For patients with evidence of active or latent tuberculosis, consult a physician with expertise in the treatment of tuberculosis before starting Jakafi. The decision to continue Jakafi during treatment of active tuberculosis should be based on the overall risk-benefit determination. *Progressive Multifocal Leukoencephalopathy* Progressive multifocal leukoencephalopathy (PML) has occurred with Jakafi treatment. If PML is suspected, stop Jakafi and evaluate. *Herpes Zoster* Advise patients about early signs and symptoms of herpes zoster and to seek treatment as early as possible if suspected [*see Adverse Reactions (6.1) in Full Prescribing Information*]. *Hepatitis B* Hepatitis B viral load (HBV-DNA titer) increases, with or without associated elevations in alanine aminotransferase and aspartate aminotransferase, have been reported in patients with chronic HBV infections taking Jakafi. The effect of Jakafi on viral replication in patients with chronic HBV infection is unknown. Patients with chronic HBV infection should be treated and monitored according to clinical guidelines. **Symptom Exacerbation Following Interruption or Discontinuation of Treatment with Jakafi** Following discontinuation of Jakafi, symptoms from myeloproliferative neoplasms may return to pretreatment levels over a period of approximately one week. Some patients with MF have experienced one or more of the following adverse events after discontinuing Jakafi: fever, respiratory distress, hypotension, DIC, or multi-organ failure. If one or more of these occur after discontinuation of, or while tapering the dose of Jakafi, evaluate for and treat any intercurrent illness and consider restarting or increasing the dose of Jakafi. Instruct patients not to interrupt or discontinue Jakafi therapy without consulting their physician. When discontinuing or interrupting therapy with Jakafi for reasons other than thrombocytopenia or neutropenia [*see Dosage and Administration (2.6) in Full Prescribing Information*], consider tapering the dose of Jakafi gradually rather than discontinuing abruptly. **Non-Melanoma Skin Cancer** Non-melanoma skin cancers including basal cell, squamous cell, and Merkel cell carcinoma have occurred in patients treated with Jakafi. Perform periodic skin examinations. **Lipid Elevations** Treatment with Jakafi has been associated with increases in lipid parameters including total cholesterol, low-density lipoprotein (LDL) cholesterol, and triglycerides. The effect of these lipid parameter elevations on cardiovascular morbidity and mortality has not been determined in patients treated with Jakafi. Assess lipid parameters approximately 8-12 weeks following initiation of Jakafi therapy. Monitor and treat according to clinical guidelines for the management of hyperlipidemia. **ADVERSE REACTIONS** The following clinically significant adverse reactions are discussed in greater detail in other sections of the labeling: • Thrombocytopenia, Anemia and Neutropenia [*see Warnings and Precautions (5.1) in Full Prescribing Information*] • Risk of Infection [*see Warnings and Precautions (5.2) in Full Prescribing Information*] • Symptom Exacerbation Following Interruption or Discontinuation of Treatment with Jakafi [*see Warnings and Precautions (5.3) in Full Prescribing Information*] • Non-Melanoma Skin Cancer [*see Warnings and Precautions (5.4) in Full Prescribing Information*]. **Clinical Trials Experience in Myelofibrosis** 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 Jakafi was assessed in 617 patients in six clinical studies with a median duration of follow-up of 10.9 months, including 301 patients with MF in two Phase 3 studies. In these two Phase 3 studies, patients had a median duration of exposure to Jakafi of 9.5 months (range 0.5 to 17 months), with 89% of patients treated for more than 6 months and 25% treated for more than 12 months. One hundred and eleven (111) patients started treatment at 15 mg twice daily and 190 patients started at 20 mg twice daily. In patients starting treatment with 15 mg twice daily (pretreatment platelet counts of 100 to 200×10^9/L) and 20 mg twice daily (pretreatment platelet counts greater than 200×10^9/L), 65% and 25% of patients, respectively, required a dose reduction below the starting dose within the first 8 weeks of therapy. In a double-blind, randomized, placebo-controlled study of Jakafi, among the 155 patients treated with Jakafi, the most frequent adverse reactions were thrombocytopenia and anemia [*see Table 2*]. Thrombocytopenia, anemia and neutropenia are dose-related effects. The three most frequent nonhematologic adverse reactions were bruising, dizziness and headache [*see Table 1*]. Discontinuation for adverse events, regardless of causality, was observed in 11% of patients treated with Jakafi and 11% of patients treated with placebo. Table 1 presents the most common nonhematologic adverse reactions occurring in patients who received Jakafi in the double-blind, placebo-controlled study during randomized treatment.

Table 1: Myelofibrosis: Nonhematologic Adverse Reactions Occurring in Patients on Jakafi in the Double-blind, Placebo-controlled Study During Randomized Treatment

	Jakafi (N=155)			Placebo (N=151)		
Adverse Reactions	**All Grades[a] (%)**	**Grade 3 (%)**	**Grade 4 (%)**	**All Grades (%)**	**Grade 3 (%)**	**Grade 4 (%)**
Bruising[b]	23	<1	0	15	0	0
Dizziness[c]	18	<1	0	7	0	0
Headache	15	0	0	5	0	0
Urinary Tract Infections[d]	9	0	0	5	<1	<1
Weight Gain[e]	7	<1	0	1	<1	0
Flatulence	5	0	0	<1	0	0
Herpes Zoster[f]	2	0	0	<1	0	0

[a] National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 3.0
[b] includes contusion, ecchymosis, hematoma, injection site hematoma, periorbital hematoma, vessel puncture site hematoma, increased tendency to bruise, petechiae, purpura
[c] includes dizziness, postural dizziness, vertigo, balance disorder, Meniere's Disease, labyrinthitis
[d] includes urinary tract infection, cystitis, urosepsis, urinary tract infection bacterial, kidney infection, pyuria, bacteria urine, bacteria urine identified, nitrite urine present
[e] includes weight increased, abnormal weight gain
[f] includes herpes zoster and post-herpetic neuralgia

Description of Selected Adverse Reactions: Anemia In the two Phase 3 clinical studies, median time to onset of first CTCAE Grade 2 or higher anemia was approximately 6 weeks. One patient (<1%) discontinued treatment because of anemia. In patients receiving Jakafi, mean decreases in hemoglobin reached a nadir of approximately 1.5 to 2.0 g/dL below baseline after 8 to 12 weeks of therapy and then gradually recovered to reach a new steady state that was approximately 1.0 g/dL below baseline. This pattern was observed in patients regardless of whether they had received transfusions during therapy. In the randomized, placebo-controlled study, 60% of patients treated with Jakafi and 38% of patients receiving placebo received red blood cell transfusions during randomized treatment. Among transfused patients, the median number of units transfused per month was 1.2 in patients treated with Jakafi and 1.7 in placebo treated patients. **Thrombocytopenia** In the two Phase 3 clinical studies, in patients who developed Grade 3 or 4 thrombocytopenia, the median time to onset was approximately 8 weeks. Thrombocytopenia was generally reversible with dose reduction or dose interruption. The median time to recovery of platelet counts above 50×10^9/L was 14 days. Platelet transfusions were administered to 5% of patients receiving Jakafi and to 4% of patients receiving control regimens. Discontinuation of treatment because of thrombocytopenia occurred in <1% of patients receiving Jakafi and <1% of patients receiving control regimens. Patients with a platelet count of 100×10^9/L to 200×10^9/L before starting Jakafi had a higher frequency of Grade 3 or 4 thrombocytopenia compared to patients with a platelet count greater than 200×10^9/L (17% versus 7%). **Neutropenia** In the two Phase 3 clinical studies, 1% of patients reduced or stopped Jakafi because of neutropenia. Table 2 provides the frequency and severity of clinical hematology abnormalities reported for patients receiving treatment with Jakafi or placebo in the placebo-controlled study.

Table 2: Myelofibrosis: Worst Hematology Laboratory Abnormalities in the Placebo-Controlled Study[a]

	Jakafi (N=155)			Placebo (N=151)		
Laboratory Parameter	**All Grades[b] (%)**	**Grade 3 (%)**	**Grade 4 (%)**	**All Grades (%)**	**Grade 3 (%)**	**Grade 4 (%)**
Thrombocytopenia	70	9	4	31	1	0
Anemia	96	34	11	87	16	3
Neutropenia	19	5	2	4	<1	1

[a] Presented values are worst Grade values regardless of baseline
[b] National Cancer Institute Common Terminology Criteria for Adverse Events, version 3.0

Additional Data from the Placebo-Controlled Study • 25% of patients treated with Jakafi and 7% of patients treated with placebo developed newly occurring or worsening Grade 1 abnormalities in alanine transaminase (ALT). The incidence of greater than or equal to Grade 2 elevations was 2% for Jakafi with 1% Grade 3 and no Grade 4 ALT elevations. • 17% of patients treated with Jakafi and 6% of patients treated with placebo developed newly occurring or worsening Grade 1 abnormalities in aspartate transaminase (AST). The incidence of Grade 2 AST elevations was <1% for Jakafi with no Grade 3 or 4 AST elevations. • 17% of patients treated with Jakafi and <1% of patients treated with placebo developed newly occurring or worsening Grade 1 elevations in cholesterol. The incidence of Grade 2 cholesterol elevations was <1% for Jakafi with no Grade 3 or 4 cholesterol elevations. **Clinical Trial Experience in Polycythemia Vera** In a randomized, open-label, active-controlled study, 110 patients with PV resistant to or intolerant of hydroxyurea received Jakafi and 111 patients received best available therapy [*see Clinical Studies (14.2) in Full Prescribing Information*]. The most frequent adverse reaction was anemia. Discontinuation for adverse events, regardless of causality, was observed in 4% of patients treated with Jakafi. Table 3 presents the most frequent nonhematologic adverse reactions occurring up to Week 32.

Table 3: Polycythemia Vera: Nonhematologic Adverse Reactions Occurring in ≥ 5% of Patients on Jakafi in the Open-Label, Active-controlled Study up to Week 32 of Randomized Treatment

	Jakafi (N=110)		Best Available Therapy (N=111)	
Adverse Reactions	**All Grades[a] (%)**	**Grade 3-4 (%)**	**All Grades (%)**	**Grade 3-4 (%)**
Diarrhea	15	0	7	<1
Dizziness[b]	15	0	13	0
Dyspnea[c]	13	3	4	0
Muscle Spasms	12	<1	5	0
Constipation	8	0	3	0
Herpes Zoster[d]	6	<1	0	0

Table 3 continued above.

Table 3 continued.

	Jakafi (N=110)		Best Available Therapy (N=111)	
Adverse Reactions	**All Grades[a] (%)**	**Grade 3-4 (%)**	**All Grades (%)**	**Grade 3-4 (%)**
Nausea	6	0	4	0
Weight Gain[e]	6	0	<1	0
Urinary Tract Infections[f]	6	0	3	0
Hypertension	5	<1	3	<1

[a] National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 3.0
[b] includes dizziness and vertigo
[c] includes dyspnea and dyspnea exertional
[d] includes herpes zoster and post-herpetic neuralgia
[e] includes weight increased and abnormal weight gain
[f] includes urinary tract infection and cystitis

Clinically relevant laboratory abnormalities are shown in Table 4.

Table 4: Polycythemia Vera: Selected Laboratory Abnormalities in the Open-Label, Active-controlled Study up to Week 32 of Randomized Treatment[a]

	Jakafi (N=110)			Best Available Therapy (N=111)		
Laboratory Parameter	**All Grades[b] (%)**	**Grade 3 (%)**	**Grade 4 (%)**	**All Grades (%)**	**Grade 3 (%)**	**Grade 4 (%)**
Hematology						
Anemia	72	<1	<1	58	0	0
Thrombocytopenia	27	5	<1	24	3	<1
Neutropenia	3	0	<1	10	<1	0
Chemistry						
Hypercholesterolemia	35	0	0	8	0	0
Elevated ALT	25	<1	0	16	0	0
Elevated AST	23	0	0	23	<1	0
Hypertriglyceridemia	15	0	0	13	0	0

[a] Presented values are worst Grade values regardless of baseline
[b] National Cancer Institute Common Terminology Criteria for Adverse Events, version 3.0

Clinical Trial Experience in Acute Graft-Versus-Host Disease In a single-arm, open-label study, 71 adults (ages 18-73 years) were treated with Jakafi for acute GVHD failing treatment with steroids with or without other immunosuppressive drugs [see *Clinical Studies (14.3) in Full Prescribing Information*]. The median duration of treatment with Jakafi was 46 days (range, 4-382 days). There were no fatal adverse reactions to Jakafi. An adverse reaction resulting in treatment discontinuation occurred in 31% of patients. The most common adverse reaction leading to treatment discontinuation was infection (10%). Table 5 shows the adverse reactions other than laboratory abnormalities.

Table 5: Acute Graft-Versus-Host Disease: Nonhematologic Adverse Reactions Occurring in ≥ 15% of Patients in the Open-Label, Single-Cohort Study

	Jakafi (N=71)	
Adverse Reactions[a]	**All Grades[b] (%)**	**Grade 3-4 (%)**
Infections	55	41
Edema	51	13
Hemorrhage	49	20
Fatigue	37	14
Bacterial infections	32	28
Dyspnea	32	7
Viral infections	31	14
Thrombosis	25	11
Diarrhea	24	7
Rash	23	3
Headache	21	4
Hypertension	20	13
Dizziness	16	0

[a] Selected laboratory abnormalities are listed in Table 6 below
[b] National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 4.03

Selected laboratory abnormalities during treatment with Jakafi are shown in Table 6.

Table 6: Acute Graft-Versus-Host Disease: Selected Laboratory Abnormalities Worsening from Baseline in the Open-Label, Single Cohort Study

	Jakafi (N=71)	
	Worst grade during treatment	
Laboratory Parameter	**All Grades[a] (%)**	**Grade 3-4 (%)**
Hematology		
Anemia	75	45
Thrombocytopenia	75	61
Neutropenia	58	40
Chemistry		
Elevated ALT	48	8
Elevated AST	48	6
Hypertriglyceridemia	11	1

[a] National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03

DRUG INTERACTIONS Fluconazole Concomitant administration of Jakafi with fluconazole doses greater than 200 mg daily may increase ruxolitinib exposure due to inhibition of both the CYP3A4 and CYP2C9 metabolic pathways [*see Clinical Pharmacology (12.3) in Full Prescribing Information*]. Increased exposure may increase the risk of exposure-related adverse reactions. Avoid the concomitant use of Jakafi with fluconazole doses of greater than 200 mg daily except in patients with acute GVHD [*see Dosage and Administration (2.4) in Full Prescribing Information*]. **Strong CYP3A4 inhibitors** Concomitant administration of Jakafi with strong CYP3A4 inhibitors increases ruxolitinib exposure [*see Clinical Pharmacology (12.3) in Full Prescribing Information*]. Increased exposure may increase the risk of exposure-related adverse reactions. Consider dose reduction when administering Jakafi with strong CYP3A4 inhibitors [*see Dosage and Administration (2.4) in Full Prescribing Information*]. In patients with acute GVHD, reduce Jakafi dose as recommended only when coadministered with ketoconazole, and monitor blood counts more frequently for toxicity and adjust the dose if necessary when coadministered with itraconazole. [*see Dosage and Administration (2.4) in Full Prescribing Information*]. **Strong CYP3A4 inducers** Concomitant administration of Jakafi with strong CYP3A4 inducers may decrease ruxolitinib exposure [*see Clinical Pharmacology (12.3) in Full Prescribing Information*]. No dose adjustment is recommended; however, monitor patients frequently and adjust the Jakafi dose based on safety and efficacy [*see Clinical Pharmacology (12.3) in Full Prescribing Information*]. **USE IN SPECIFIC POPULATIONS** **Pregnancy: Risk Summary** When pregnant rats and rabbits were administered ruxolitinib during the period of organogenesis adverse developmental outcomes occurred at doses associated with maternal toxicity (*see Data*). There are no studies with the use of Jakafi in pregnant women to inform drug-associated risks. The background risk of major birth defects and miscarriage for the indicated populations is unknown. Adverse outcomes in pregnancy occur regardless of the health of the mother or the use of medications. The background risk in the U.S. general population of major birth defects is 2% to 4% and miscarriage is 15% to 20% of clinically recognized pregnancies. **Data:** *Animal Data* Ruxolitinib was administered orally to pregnant rats or rabbits during the period of organogenesis, at doses of 15, 30 or 60 mg/kg/day in rats and 10, 30 or 60 mg/kg/day in rabbits. There were no treatment-related malformations. Adverse developmental outcomes, such as decreases of approximately 9% in fetal weights were noted in rats at the highest and maternally toxic dose of 60 mg/kg/day. This dose results in an exposure (AUC) that is approximately 2 times the clinical exposure at the maximum recommended dose of 25 mg twice daily. In rabbits, lower fetal weights of approximately 8% and increased late resorptions were noted at the highest and maternally toxic dose of 60 mg/kg/day. This dose is approximately 7% the clinical exposure at the maximum recommended dose. In a pre- and post-natal development study in rats, pregnant animals were dosed with ruxolitinib from implantation through lactation at doses up to 30 mg/kg/day. There were no drug-related adverse findings in pups for fertility indices or for maternal or embryofetal survival, growth and development parameters at the highest dose evaluated (34% the clinical exposure at the maximum recommended dose of 25 mg twice daily). **Lactation: Risk Summary** No data are available regarding the presence of ruxolitinib in human milk, the effects on the breast fed child, or the effects on milk production. Ruxolitinib and/or its metabolites were present in the milk of lactating rats (*see Data*). Because many drugs are present in human milk and because of the potential for thrombocytopenia and anemia shown for Jakafi in human studies, discontinue breastfeeding during treatment with Jakafi and for two weeks after the final dose. **Data:** *Animal Data* Lactating rats were administered a single dose of [^{14}C]-labeled ruxolitinib (30 mg/kg) on postnatal Day 10, after which plasma and milk samples were collected for up to 24 hours. The AUC for total radioactivity in milk was approximately 13-fold the maternal plasma AUC. Additional analysis showed the presence of ruxolitinib and several of its metabolites in milk, all at levels higher than those in maternal plasma. **Pediatric Use** The safety and effectiveness of Jakafi for treatment of myelofibrosis or polycythemia vera in pediatric patients have not been established. The safety and effectiveness of Jakafi for treatment of steroid-refractory acute graft-versus-host disease (GVHD) have been established for treatment of children 12 years and older. Use of Jakafi in pediatric patients with steroid-refractory acute GVHD is supported by evidence from an adequate and well-controlled trial of Jakafi in adults [*see Clinical Studies (14.3) in Full Prescribing Information*] and additional pharmacokinetic and safety data in pediatric patients. Jakafi was evaluated in a single-arm, dose-escalation study (NCT01164163) in 27 pediatric patients with relapsed or refractory solid tumors (Cohort A) and 20 with leukemias or myeloproliferative neoplasms (Cohort B). The patients had a median age of 14 years (range, 2 to 21 years) and included 18 children (age 2 to <12 years), and 14 adolescents (age 12 to <17 years). The dose levels tested were 15, 21, 29, 39, or 50 mg/m^2 twice daily in 28-day cycles with up to 6 patients per dose group. Overall, 38 (81%) patients were treated with no more than a single cycle of Jakafi, while 3, 1, 2, and 3 patients received 2, 3, 4, and 5 or more cycles, respectively. A protocol-defined maximal tolerated dose was not observed, but since few patients were treated for multiple cycles, tolerability with continued use was not assessed adequately to establish a recommended Phase 2 dose higher than the recommended dose for adults. The safety profile in children was similar to that seen in adults. *Juvenile Animal Toxicity Data* Administration of ruxolitinib to juvenile rats resulted in effects on growth and bone measures. When administered starting at postnatal day 7 (the equivalent of a human newborn) at doses of 1.5 to 75 mg/kg/day, evidence of fractures occurred at doses ≥ 30 mg/kg/day, and effects on body weight and other bone measures [e.g., bone mineral content, peripheral quantitative computed tomography, and x-ray analysis] occurred at doses ≥ 5 mg/kg/day. When administered starting at postnatal day 21 (the equivalent of a human 2-3 years of age) at doses of 5 to 60 mg/kg/day, effects on body weight and bone occurred at doses ≥ 15 mg/kg/day, which were considered adverse at 60 mg/kg/day. Males were more severely affected than females in all age groups, and effects were generally more severe when administration was initiated earlier in the postnatal period. These findings were observed at exposures that are at least 27% the clinical exposure at the maximum recommended dose of 25 mg twice daily. **Geriatric Use** Of the total number of patients with MF in clinical studies with Jakafi, 52% were 65 years and older, while 15% were 75 years and older. No overall differences in safety or effectiveness of Jakafi were observed between these patients and younger patients. Clinical studies of Jakafi in patients with acute GVHD did not include sufficient numbers of subjects age 65 and over to determine whether they respond differently from younger subjects. **Renal Impairment** Total exposure of ruxolitinib and its active metabolites increased with moderate (CLcr 30 mL/min to 59 mL/min) and severe (CLcr 15 mL/min to 29 mL/min) renal impairment, and ESRD on dialysis [*see Clinical Pharmacology (12.3) in Full Prescribing Information*]. Reduce Jakafi dose as recommended [*see Dosage and Administration (2.5) in Full Prescribing Information*]. **Hepatic Impairment** Exposure of ruxolitinib increased with mild (Child-Pugh A), moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment [*see Clinical Pharmacology (12.3) in Full Prescribing Information*]. Reduce Jakafi dose as recommended in patients with MF or PV and any hepatic impairment [*see Dosage and Administration (2.5) in Full Prescribing Information*]. Monitor blood counts more frequently for toxicity and consider 5 mg once daily for patients with Stage 3 or 4 liver GVHD [*see Dosage and Administration (2.5) and Clinical Pharmacology (12.3) in Full Prescribing Information*]. **OVERDOSAGE** There is no known antidote for overdoses with Jakafi. Single doses up to 200 mg have been given with acceptable acute tolerability. Higher than recommended repeat doses are associated with increased myelosuppression including leukopenia, anemia and thrombocytopenia. Appropriate supportive treatment should be given. Hemodialysis is not expected to enhance the elimination of Jakafi.

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