

For the short-term, non-continuous chronic treatment of mild to moderate eczema (atopic dermatitis) not well controlled on topical prescription therapies or when those therapies are not recommended in people 12 and older without weakened immune systems.



#### IMPORTANT SAFETY INFORMATION

OPZELURA may cause serious side effects, including:

Serious Infections: OPZELURA contains ruxolitinib. Ruxolitinib belongs to a class of medicines called Janus kinase (JAK) inhibitors. JAK inhibitors are medicines that affect your immune system. JAK inhibitors can lower the ability of your immune system to fight infections. Some people have had serious infections while taking JAK inhibitors by mouth, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have been hospitalized or died from these infections. Some people have had serious infections of their lungs while taking OPZELURA. Your healthcare provider should watch you closely for signs and symptoms of TB during treatment with OPZELURA.

# Opzelura\* (ruxolitinib) cream 1.5%

# IMAGINE HAVING ECZEMA RELIEF AT YOUR FINGERTIPS

IT'S NOT IMAGINARY, IT'S OPZELURA.



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# IF I COULD USE ONE WORD TO DESCRIBE OPZELURA, I WOULD SAY RELIEF."

- Cameron, OPZELURA patient

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#### INDICATION AND USAGE

OPZELURA is a prescription medicine used on the skin (topical) for the short-term and non-continuous chronic treatment of mild to moderate eczema (atopic dermatitis) in non-immunocompromised adults and children 12 years of age and older whose disease is not well controlled with topical prescription therapies or when those therapies are not recommended.

The use of OPZELURA along with therapeutic biologics, other JAK inhibitors, or strong immunosuppressants such as azathioprine or cyclosporine is not recommended.

It is not known if OPZELURA is safe and effective in children less than 12 years of age with atopic dermatitis.

### GET TO KNOW OPZELURA

OPZELURA is a single steroid-free cream applied directly to the areas of the skin where you have eczema,\* and seamlessly goes on to help reduce itch right where it's needed. Use OPZELURA as directed by your healthcare provider.

\*OPZELURA is for use on the skin only. Do not use OPZELURA in your eyes, mouth, or vagina.



OPZELURA is applied twice daily where you need it for eczema flare-ups. You should stop using OPZELURA when symptoms clear.

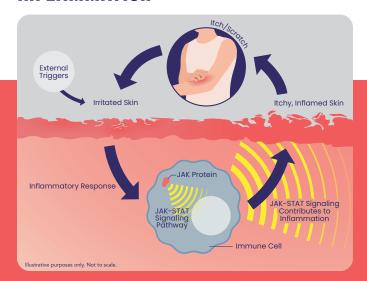
#### **IMPORTANT SAFETY INFORMATION (CONT.)**

OPZELURA may cause serious side effects, including:

Serious Infections (cont.): OPZELURA should not be used in people with an active, serious infection, including localized infections. You should not start using OPZELURA if you have any kind of infection unless your healthcare provider tells you it is okay. You may be at a higher risk of developing shingles (herpes zoster) while using OPZELURA.

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# A DEEPER LOOK AT ECZEMA INFLAMMATION

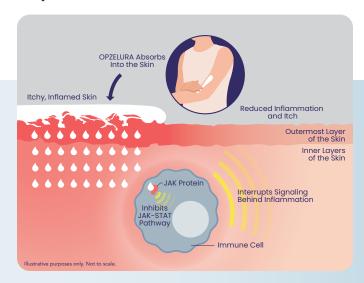


Eczema actually starts below the surface with research findings suggesting that people with eczema have an imbalance in part of their immune system, causing too much inflammation in the body.

Inflammation is what causes eczema symptoms like rash, itchiness, and bumpy skin that may appear red, purple, or ashen gray.

Scratching that itch creates even more inflammation, which in turn causes more itch and rash. This is called the itch-scratch cycle—it often repeats and can worsen without treatment.

## **SO, HOW DOES OPZELURA WORK?**



In people with eczema, a system called the JAK-STAT pathway may be out of balance, contributing to inflammation and itch throughout the body. OPZELURA is an on-the-spot topical cream that targets the JAK-STAT pathway, which is believed to help regulate signaling behind the inflammation that causes eczema itch.

The exact way that OPZELURA works to reduce signs and symptoms of eczema is not fully understood.

## GET A CLOSER LOOK AT HOW OPZELURA WORKS

Scan to watch this video and learn more from dermatologist Dr. Rocco Serrao.



#### **IMPORTANT SAFETY INFORMATION (CONT.)**

Increased risk of death due to any reason (all causes): Increased risk of death has happened in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor and are taking a medicine in the class of medicines called JAK inhibitors by mouth.

### HELP KICK THE ITCH-WITH OPZELURA



OPZELURA was studied in two clinical trials of people with mild to moderate eczema ages 12 years and older with a range of skin tones—and was shown to help clear the visible signs of eczema and significantly reduce itch.

#### **IMPORTANT SAFETY INFORMATION (CONT.)**

Cancer and immune system problems: OPZELURA may increase your risk of certain cancers by changing the way your immune system works. Lymphoma and other cancers have happened in people taking a medicine in the class of medicines called JAK inhibitors by mouth. People taking JAK inhibitors by mouth have a higher risk of certain cancers including lymphoma and lung cancer, especially if they are a current or past smoker.



#### IN A CLINICAL STUDY



# MORE THAN HALF OF PATIENTS ACHIEVED CLEAR OR ALMOST CLEAR SKIN AFTER

### 8 WEEKS

Skin clearance

54% of those using OPZELURA achieved clear or almost clear skin at Week 8 compared to 15% of those not using OPZELURA.



MORE THAN HALF OF PATIENTS ACHIEVED MEANINGFUL ITCH RELIEF AT WEEK 8

**Itch relief** 

52% of those using OPZELURA achieved meaningful itch relief at Week 8 compared to 15% of those not using OPZELURA.

Similar results were seen in another clinical study.

#### **FAST RESULTS**

Some saw rapid itch improvement in as early as 3 to 4 days.



Ask your doctor about using OPZELURA with other products like moisturizer, sunscreen, deodorant, etc.

#### **IMPORTANT SAFETY INFORMATION (CONT.)**

Cancer and immune system problems (cont.):

Some people have had skin cancers while using OPZELURA. Your healthcare provider will regularly check your skin during your treatment with OPZELURA. Limit the amount of time you spend in the sunlight. Wear protective clothing when you are in the sun and use a broad-spectrum sunscreen.





In clinical studies, OPZELURA was shown to help clear visible signs of mild to moderate eczema after 8 weeks.

The following photos are from actual patients who participated in the clinical study. OPZELURA was not studied in patients with severe eczema.



Individual results may vary.

#### **IMPORTANT SAFETY INFORMATION (CONT.)**

Increased risk of major cardiovascular events:

Increased risk of major cardiovascular events such as heart attack, stroke, or death have happened in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor and taking a medicine in the class of medicines called JAK inhibitors by mouth, especially in current or past smokers.





Get ready for your next appointment

Scan to start The Eczema Eight\* and prepare for your visit.

\*Please note The Eczema Eight is a tool to aid discussions with your healthcare provider. It is not intended to diagnose or measure eczema severity. Follow guidance from your healthcare provider.

#### **IMPORTANT SAFETY INFORMATION (CONT.)**

**Blood clots:** Blood clots in the veins of your legs (deep vein thrombosis, DVT) or lungs (pulmonary embolism, PE) can happen in some people taking OPZELURA. This may be life-threatening. Blood clots in the vein of the legs (deep vein thrombosis, DVT) and lungs (pulmonary embolism, PE) have happened more often in people who are 50 years of age and older and with at least 1 heart disease (cardiovascular) risk factor taking a medicine in the class of medicines called JAK inhibitors by mouth.





### **SUPPORT THAT'S TRULY YOURS**

Designed for people with mild to moderate eczema who are prescribed OPZELURA, the Yours Truly program connects you with resources and guidance at every step along your way. Just by signing up, you can rest assured you'll have help along your treatment journey with OPZELURA. Imagine that.

COPAY SAVINGS CARD





#### **SEE IF YOU QUALIFY**

Scan to go directly to the OPZELURA Copay Savings Program page.

\*Eligibility required. For use only with commercial prescription insurance. The card may not be used if the patient is enrolled in a government-funded prescription insurance program or if they pay cash for their prescription. Individual out-of-pocket cost may vary. Maximum benefits per tube and per calendar year apply. Must be used for an FDA-approved indication. Review additional Terms and Conditions by visiting opzelura.com and selecting the patient's condition.

## Opzelura® (ruxolitinib) cream 1.5%



### OPZELURA YOURS TRULY SUPPORT INCLUDES:



#### **Getting started with OPZELURA:**

Find information to help you understand how OPZELURA works and learn more about how to use it.



#### How to stay on track:

Access tips and tools that will help you incorporate OPZELURA into your daily routine, track your journey, and share your progress with your healthcare provider.

SCAN TO LEARN MORE ABOUT HOW OPZELURA YOURS TRULY CAN HELP SUPPORT YOU.



#### LEARN ABOUT ADDITIONAL FINANCIAL SUPPORT

IncyteCARES is a patient support program designed to help you understand your insurance coverage and determine eligibility for financial assistance. Visit incytecares.com or call 1-800-583-6964 for more information.



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Low blood cell counts: OPZELURA may cause low platelet counts (thrombocytopenia), low red blood cell counts (anemia), and low white blood cell counts (neutropenia). If needed, your healthcare provider will do a blood test to check your blood cell counts during your treatment with OPZELURA and may stop your treatment if signs or symptoms of low blood cell counts happen.

**Cholesterol increases:** Cholesterol increase has happened in people when ruxolitinib is taken by mouth. Tell your healthcare provider if you have high cholesterol or triglycerides.

### Before starting OPZELURA, tell your healthcare provider if you:

- have an infection, are being treated for one, or have had an infection that does not go away or keeps coming back
- have diabetes, chronic lung disease, HIV, or a weak immune system
- have TB or have been in close contact with someone with TB
- have had shingles (herpes zoster)
- · have or have had hepatitis B or C
- live, have lived in, or have traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased chance for getting certain kinds of fungal infections. These infections may happen



# IMPORTANT SAFETY INFORMATION (CONT.)

or become more severe if you use OPZELURA. Ask your healthcare provider if you do not know if you have lived in an area where these infections are common.

- think you have an infection or have symptoms of an infection such as: fever, sweating, or chills, muscle aches, cough or shortness of breath, blood in your phlegm, weight loss, warm, red, or painful skin or sores on your body, diarrhea or stomach pain, burning when you urinate or urinating more often than usual, feeling very tired.
- have ever had any type of cancer, or are a current or past smoker
- have had a heart attack, other heart problems, or a stroke
- have had blood clots in the veins of your legs or lungs in the past
- · have high cholesterol or triglycerides
- · have or have had low white or red blood cell counts
- are pregnant or plan to become pregnant. It is not known if OPZELURA will harm your unborn baby. There is a pregnancy exposure registry for individuals who use OPZELURA during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. If you become exposed to OPZELURA during pregnancy, you and your healthcare provider should report exposure to Incyte Corporation at 1-855-463-3463.
- are breastfeeding or plan to breastfeed. It is not known if OPZELURA passes into your breast milk. Do not breastfeed during treatment with OPZELURA and for about 4 weeks after the last dose.

#### After starting OPZELURA:

- Call your healthcare provider right away if you have any symptoms of an infection. OPZELURA can make you more likely to get infections or make worse any infections that you have.
- Get emergency help right away if you have any symptoms of a heart attack or stroke while using OPZELURA, including:
  - discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back

- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw, or stomach
- shortness of breath with or without chest discomfort
- o breaking out in a cold sweat
- o nausea or vomiting
- o feeling lightheaded
- weakness in one part or on one side of your body
- slurred speech
- Tell your healthcare provider right away if you have any signs and symptoms of blood clots during treatment with OPZELURA, including: swelling, pain, or tenderness in one or both legs, sudden, unexplained chest or upper back pain, or shortness of breath or difficulty breathing.
- Tell your healthcare provider right away if you develop or have worsening of any symptoms of low blood cell counts, such as: unusual bleeding, bruising, tiredness, shortness of breath, or fever.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

The most common side effects of OPZELURA in people treated for atopic dermatitis include: common cold (nasopharyngitis), diarrhea, bronchitis, ear infection, increase in a type of white blood cell (eosinophil) count, hives, inflamed hair pores (folliculitis), swelling of the tonsils (tonsillitis), and runny nose (rhinorrhea).

These are not all of the possible side effects of OPZELURA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Incyte Corporation at 1-855-463-3463.

Please see the <u>Full Prescribing Information</u>, including Boxed Warning, and <u>Medication Guide</u> for OPZELURA



Please see Important Safety Information on pages 12-15 and the Full Prescribing Information, including Boxed Warning, and Medication Guide for OPZELURA.



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