

#### 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.

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



# ✓ YOUR SKIN.✓ YOUR RESULTS.✓ YOUR SUPPORT.

TIPS & TREATMENT TRACKING MADE TRULY FOR YOU.

Imagine this: a guide created to support you as OPZELURA works to clear or almost clear skin and help kick the itch. Flip through for tips to help you get started on your treatment journey, as well as a tracker to help you remember your applications during a flare-up.

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

Serious Infections (cont.): 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.



#### PROVEN RESULTS. PROVEN RELIEF.

The data is in! We'll let the results speak for themselves:



#### **RELIEF AND CLARITY AT YOUR FINGERTIPS**

OPZELURA was studied in two clinical trials of people with mild to moderate eczema ages 12 and older. More than half of patients achieved clear or almost clear skin and meaningful itch relief at 8 weeks. Some even saw itch improvement as early as 3 or 4 days.



#### **RESULTS AT ONE YEAR**

After 8 weeks, patients were given the choice to continue using OPZELURA as needed if their eczema signs and symptoms returned for up to one year.\*

Over 75% of patients had clear or almost clear skin at one year when they used OPZELURA as needed.

In clinical studies, the most common side effects (\$2%) of OPZELURA included: upper respiratory tract infection, common cold (nasopharyngitis), headache, bronchitis, influenza, inflammation of the nasal passages (rhinitis), atopic dermatitis, and asthma.

\*This was a less rigorous part of the study where patients and their physicians knew they were using an active treatment, which could have affected the results.

#### **IMPORTANT SAFETY INFORMATION (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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TIPS

### **SETTING UP FOR SUCCESS:**

BEFORE STARTING TREATMENT, LEARN SOME TIPS THAT MAY HELP YOU ALONG YOUR JOURNEY.

#### THE DOS AND DON'TS

Apply a thin layer of OPZELURA twice daily to affected areas on up to 20% of body surface area (BSA) as directed by your healthcare provider. OPZELURA is for use on the skin only. Do not use OPZELURA in your eyes, mouth, or vagina. Do not use more than one 60-gram tube each week.

Stop using when signs and symptoms of eczema resolve. If signs and symptoms do not improve within 8 weeks, contact your dermatologist.



#### A HELPING HAND

If you're uncertain about what 20% of your BSA looks like, use your hand to estimate. Generally, 1 handprint is about 1% of your BSA.



#### **HAVE A PLAN**

Even with a tracker, it might feel tricky to remember to apply OPZELURA each morning and night. Using your phone to set reminder alarms or calendar notifications can help you stay on track.

#### TRACK YOUR PROGRESS

You can use your phone to snap weekly photos of treatment areas to keep track of progress. By identifying any changes to your skin over time and creating an album to share progress with your healthcare provider, you can help streamline your journey.

#### **REVISIT AS YOU NEED TO**

Eczema is a chronic condition, so you may experience new flare-ups. OPZELURA is here for as-needed, on-the-spot treatment. When flare-ups occur, revisit the tracking section to track applications of OPZELURA and record any notes you'd like to share with your healthcare provider. Use OPZELURA exactly as directed by your healthcare provider.



SCAN FOR RESOURCES, PATIENT STORIES, AND MORE.

#### 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.

Please see additional Important Safety Information on pages 12–15, and the <u>Full Prescribing Information</u>, including Boxed Warning, and <u>Medication Guide</u> for OPZELURA.







#### TRACKER INSTRUCTIONS:

Fill in the droplets to keep track of when you apply OPZELURA each morning and night, starting with your first day of application. Try incorporating your applications into other routines you already do twice daily so it feels like part of your everyday life. Ask your doctor about using OPZELURA with other products like moisturizer, sunscreen, or deodorant.

Remember, you should stop using OPZELURA if signs and symptoms of eczema resolve, or if directed by your healthcare provider. If your symptoms don't improve after 8 weeks, check back in with your healthcare provider.

#### **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.

#### **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.

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

Fill in the droplets below as you apply OPZELURA. Take a starting point photo of your skin on day one of treatment, and a new progress photo weekly. •



#### DATE:





#### DATE



#### DATE:



#### DATE:



#### DATE:



#### DATE:



#### DATE:



#### DATE





## PAUSE & ASSESS



Hopefully, you've found the relief from eczema you were looking for. If you've used every drop on this page (i.e., up to 8 weeks of treatment) and your symptoms haven't improved, check in with your healthcare provider about the next steps of your treatment. OPZELURA is for use on the skin only. Do not use in your eyes, mouth, or vagina.

Remember, there are additional tracking droplets on the following page if you need them.

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



#### REVISIT

Here are some extra droplets just in case you need to track more applications. Eczema is a chronic condition, but OPZELURA can help flare-ups get and stay under control.

DATE:























































































DATE:







































## **NOTES**



Use this space to capture any additional thoughts, observations, or symptoms you experience as you resume treatment with OPZELURA, or any other notes of questions you have for your healthcare provider.

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

## IMPORTANT SAFETY INFORMATION AND INDICATION

#### **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.

#### **IMPORTANT SAFETY INFORMATION**

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

#### **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 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.

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.



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. 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.

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.

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.

**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

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

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- 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 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
- breaking out in a cold sweat
- · nausea or vomiting
- · 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.

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