



### INDICATION AND USAGE

OPZELURA is a prescription medicine used on the skin (topical) for short-term and non-continuous treatment of mild to moderate eczema (atopic dermatitis) in non-immunocompromised people 12 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 for atopic dermatitis, other JAK inhibitors, or strong immunosuppressants such as azathioprine or cyclosporine is not recommended.

# THE ECZEMA EIGHT

## Eight questions could help you talk to your healthcare provider about the impact that eczema has on you.

Please note that this is not a validated, official tool used to measure eczema severity or burden.

This guide can help you or your loved one feel prepared for a productive conversation with your healthcare provider. Remember to fill it out and bring it along to your next appointment. Together, you and your healthcare provider can discuss the eczema treatment plan that's right for you or your loved one.

### 1. Which eczema symptom(s) do you experience?

(Circle all that apply)

- a. Itch
- b. Dry skin
- c. Red, inflamed skin
- d. Rough or scaly patches of skin
- e. All of the above
- f. Other: \_\_\_\_\_

### 2. In the past month, how many days have you experienced these symptoms?

Check off the days on the calendar below.

S	M	T	W	T	F	S

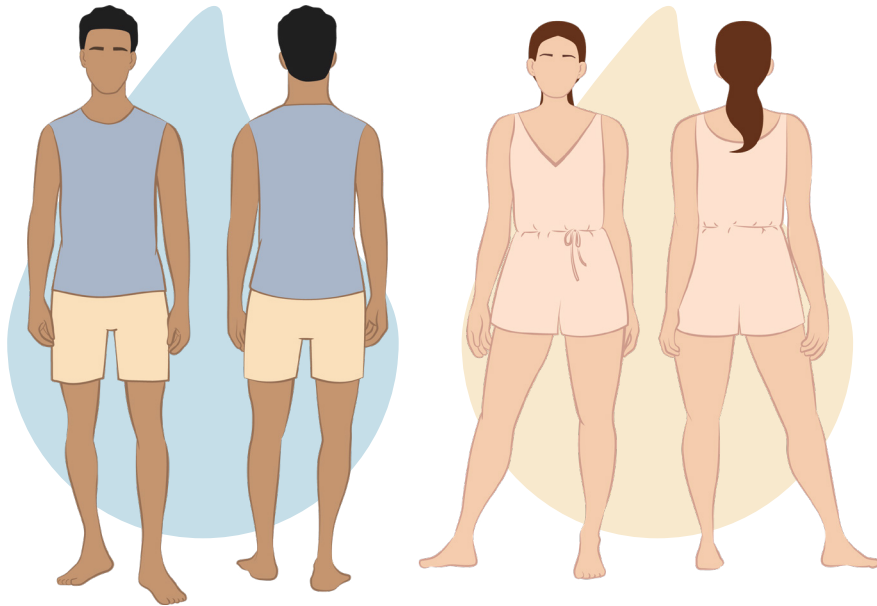
### IMPORTANT SAFETY INFORMATION

OPZELURA may cause serious side effects, including:

Serious Infections: OPZELURA cream 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.

Please see additional Important Safety Information for OPZELURA located throughout this form.

**3. Circle the areas of the body where you experience eczema most often.**



**4.  Symptom Snapshot**

Snap a photo of your eczema on days when your symptoms feel more severe to share at your next appointment. Ask if your healthcare provider has a patient portal to make sharing information easier and more secure.

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**IMPORTANT SAFETY INFORMATION (CONTINUED)**

Before starting OPZELURA, tell your healthcare provider if you:

- have an infection, are being treated for one, or have an infection that keeps coming back
- have diabetes, chronic lung disease, HIV, or a weak immune system
- have or had TB, or have been in close contact with someone with TB
- have had shingles (herpes zoster) or hepatitis B or C

Please see additional Important Safety Information for OPZELURA located throughout this form.

**5. Did you know there is a *handy* way to estimate how much of your body is covered by eczema? Use 1 hand to equal approximately 1% of your body.**



**Try this to estimate your body surface area affected by eczema and write your percentage here:**

\_\_\_\_\_

**6. How long have you had eczema symptoms?**

- a. 2-5 years
- b. 5-15 years
- c. 15+ years
- d. Other: \_\_\_\_\_

**7. Which treatments have you tried?**

(Circle all that apply)

- a. Prescription lotions and ointments
- b. Topical steroids
- c. Oral steroids
- d. Antihistamines
- e. Injections or biologics
- f. Home remedies (baths, cold compresses, diet changes, etc.)
- g. Over-the-counter moisturizers and oils
- h. All of the above
- i. Other: \_\_\_\_\_

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**IMPORTANT SAFETY INFORMATION (CONTINUED)**

The most common side effects of OPZELURA include: pain or swelling in your nose or throat (nasopharyngitis), diarrhea, bronchitis, ear infection, increase in a type of white blood cell (eosinophil) count, hives, inflamed hair pores (folliculitis), swelling of the tonsils (tonsilitis), 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 additional Important Safety Information for OPZELURA located throughout this form.

**8. What are you looking for in an eczema treatment?**

(Fill in the blank)

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**Now that you've completed the Eczema Eight assessment, you and your healthcare provider can use it to discuss your treatment options.**



OPZELURA is a steroid-free topical cream that, for many, can result in clear or almost clear skin in 8 weeks and reduced eczema itch. Your individual results may vary. Ask your healthcare provider if OPZELURA may be right for you.

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**IMPORTANT SAFETY INFORMATION**

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

OPZELURA may cause serious side effects, including:

**Serious Infections:** OPZELURA cream 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.

## IMPORTANT SAFETY INFORMATION (CONTINUED)

Increased risk of death from all causes, including sudden cardiac death, has happened in people taking 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. Some people have had lymphoma and other cancers while taking JAK inhibitors by mouth, especially if they are a current or past smoker. Some people have had skin cancers while taking OPZELURA. Your healthcare provider will regularly check your skin during your treatment with OPZELURA.

There is an increased risk of major cardiovascular events such as heart attack, stroke or cardiac death in people with cardiovascular risk factors and who are current or past smokers while using JAK inhibitors to treat inflammatory conditions.

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.

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 an infection that keeps coming back
- have diabetes, chronic lung disease, HIV, or a weak immune system
- have or had TB or have been in close contact with someone with TB
- have had shingles (herpes zoster) or 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:
  - o fever, sweating, or chills
  - o muscle aches
  - o cough or shortness of breath
  - o blood in your phlegm
  - o weight loss
  - o warm, red, or painful skin or sores on your body
  - o diarrhea or stomach pain
  - o burning when you urinate or urinating more often than usual
  - o feeling very tired
- have ever had any type of cancer, or are a current or past smoker
- 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.

## IMPORTANT SAFETY INFORMATION (CONTINUED)

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:
  - o discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
  - o severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
  - o pain or discomfort in your arms, back, neck, jaw, or stomach
  - o shortness of breath with or without chest discomfort
  - o breaking out in a cold sweat
  - o nausea or vomiting
  - o feeling lightheaded
  - o weakness in one part or on one side of your body
  - o 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.

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Please see the [Full Prescribing Information](#) and [Medication Guide](#) for OPZELURA.