

MEDICATION GUIDE
OPZELURA® (OP-zuh-LUR-ah)
(ruxolitinib) cream

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

What is the most important information I should know about OPZELURA?

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 using 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.

Before starting OPZELURA, tell your healthcare provider if you:

- are being treated for an infection
- have had an infection that does not go away or that 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 in an area, or have lived in an area, 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

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. If you get a serious infection, your healthcare provider may stop your treatment with OPZELURA until your infection is controlled.

- **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.
 - Tell your healthcare provider if you have ever had any type of cancer.

- **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 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
- **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.
 - Tell your healthcare provider if you have had blood clots in the veins of your legs or lungs in the past.
 - 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
 - shortness of breath or difficulty breathing

See **“What are the possible side effects of OPZELURA?”** for more information about side effects.

What is OPZELURA?

OPZELURA is a prescription medicine used on the skin (topical) for:

- 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 treatment of a type of vitiligo called nonsegmental vitiligo in adults and children 12 years of age and older.

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 or nonsegmental vitiligo.

Before using OPZELURA, tell your healthcare provider about all of your medical conditions, including if you:

- See **“What is the most important information I should know about OPZELURA?”**
- have an infection
- are a current or past smoker
- have had a heart attack, other heart problems, or a stroke
- have or have had low white or red blood cell counts
- have high levels of fat in your blood (high cholesterol or triglycerides)
- are pregnant or plan to become pregnant. It is not known if OPZELURA will harm your unborn baby.
 - **Pregnancy Exposure Registry.** 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.

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

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use OPZELURA?

- OPZELURA is for use on the skin only. Do not use OPZELURA in your eyes, mouth, or vagina.
- Use OPZELURA exactly as your healthcare provider tells you.
- Apply a thin layer of OPZELURA 2 times a day to affected areas. **Do not** use more than one 60 gram tube each week or more than one 100 gram tube every 2 weeks. Ask your healthcare provider if you have questions about applying OPZELURA.
- If you are using OPZELURA for atopic dermatitis, stop using OPZELURA when your signs and symptoms of atopic dermatitis, such as itching, rash, and redness go away, or as directed by your healthcare provider. Tell your healthcare provider if your symptoms do not improve within 8 weeks of treatment.
- If you are using OPZELURA for nonsegmental vitiligo, tell your healthcare provider if your treated skin does not improve within 24 weeks of treatment.
- Wash your hands after applying OPZELURA, unless hands are being treated. If someone else applies OPZELURA, they should wash their hands after applying OPZELURA.

What are the possible side effects of OPZELURA?

OPZELURA may cause serious side effects, including:

- See **“What is the most important information I should know about OPZELURA?”**
- **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. Tell your healthcare provider right away if you develop or have worsening of any of these symptoms:
 - unusual bleeding
 - bruising
 - tiredness
 - shortness of breath
 - fever
- **Cholesterol increases.** Cholesterol increase has happened in people when ruxolitinib is taken by mouth. Tell your healthcare provider if you have high levels of fat in your blood (high cholesterol or triglycerides).

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)
- runny nose (rhinorrhea)

The most common side effects of OPZELURA in people treated for nonsegmental vitiligo include:

- acne at the application site
- itching at the application site
- common cold (nasopharyngitis)
- headache
- urinary tract infection
- redness at the application site
- fever

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.

How should I store OPZELURA?

- Store OPZELURA at room temperature between 68°F to 77°F (20°C to 25°C).

Keep OPZELURA and all medicines out of the reach of children.

General information about the safe and effective use of OPZELURA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use OPZELURA for a condition for which it is not prescribed. Do not give OPZELURA to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about OPZELURA that is written for healthcare professionals.

What are the ingredients in OPZELURA?

Active ingredient: ruxolitinib phosphate

Inactive ingredients: cetyl alcohol, dimethicone 350, edetate disodium, glyceryl stearate SE, light mineral oil, medium chain triglycerides, methylparaben, phenoxyethanol, polyethylene glycol 200, polysorbate 20, propylene glycol, propylparaben, stearyl alcohol, purified water, white petrolatum, and xanthan gum.

Manufactured for: Incyte Corporation, 1801 Augustine Cut-off, Wilmington, DE 19803

OPZELURA is a registered trademark of Incyte. All rights reserved.

Patent Information: www.incyte.com/patents

For more information go to www.Opzelura.com or call 1-855-463-3463