



Opzelura[®]

(ruxolitinib) cream 1.5%

For 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.

PURSUE WHAT'S YOURS

OPZELURA IS THE FIRST AND ONLY

FDA-APPROVED PRESCRIPTION TREATMENT

FOR NONSEGMENTAL VITILIGO

TO HELP REPIGMENT SKIN.

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 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.

Please see additional Important Safety Information on pages 9-12 and the Full Prescribing Information, including Boxed Warning, and Medication Guide for OPZELURA.

A PROVEN OPTION FOR REPIGMENTATION IS HERE. PURSUE IT.

Your pursuits matter. And the pursuit for pigment is no exception. It's time you had a proven option to help restore what's yours. Only OPZELURA has been FDA-approved for nonsegmental vitiligo repigmentation (getting color back in your skin). Over time, and without steroids, OPZELURA cream may help you reclaim your pigment.

 Nonsegmental vitiligo is the most common type of vitiligo—where depigmented patches appear on both sides of the body.

INDICATION AND USAGE

OPZELURA is a prescription medicine used on the skin (topical) for 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 nonsegmental vitiligo.

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.



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. Some people have had skin cancers while using OPZELURA. Your healthcare provider will regularly check your skin during your treatment with OPZELURA.

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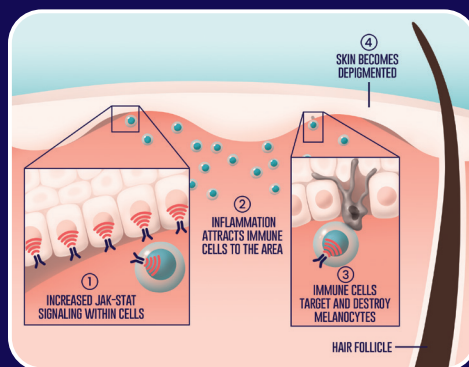
WHAT TO KNOW ABOUT OPZELURA

- It's shown to help significantly restore some skin color over time in some patients. Individual results may vary
- It's a steroid-free topical cream that you can apply yourself
- It can even be applied to sensitive areas like around the eyes, mouth, and genitals*

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

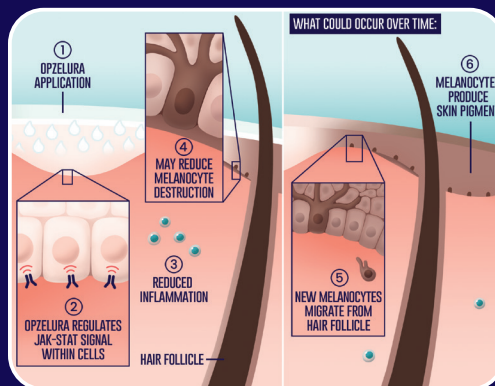


HOW DOES IT WORK?



For illustrative purposes only.

Vitiligo is more than just cosmetic. It's thought to be an autoimmune condition—where a person's overactive immune system attacks pigment-producing cells in the skin, leading to a loss of the skin's natural color.



For illustrative purposes only.

OPZELURA targets an immune signal known as the JAK-STAT pathway. This is thought to help reduce the destruction of pigment-producing cells, called melanocytes, and create an environment where repigmentation can take place over time.

IMPORTANT SAFETY INFORMATION (CONT)

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.

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.

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OPZELURA RESULTS

HOW OPZELURA WAS STUDIED

OPZELURA was studied in two clinical trials for 6 months. Participants included 674 people (450 receiving OPZELURA, 224 receiving a cream with no active ingredient) aged 12 and older, who had received a diagnosis of nonsegmental vitiligo about 15 years prior, on average. Studies of OPZELURA included males and females across a range of skin tones and ethnicities. Patients had vitiligo affecting up to 10% of their total body surface area (BSA). Phototherapy was not permitted during the trial.

IN TWO 6-MONTH CLINICAL STUDIES...

ABOUT ONE THIRD OF PARTICIPANTS SAW

75% IMPROVEMENT

IN A SCORE THAT MEASURED VITILIGO AREAS ON THE FACE.

Specifically, across two 6-month studies, the same proportion (29.9%) of those using OPZELURA achieved a 75% improvement to vitiligo areas on the face compared with 7.5% and 12.9%, respectively, of those using a non-medicated cream.

Repigmentation may continue beyond 6 months.



SCAN TO SEE

OPZELURA RESULTS

IMPORTANT SAFETY INFORMATION (CONT)

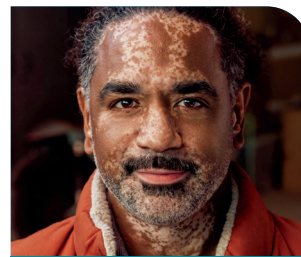
This may be life-threatening. Blood clots in the vein of the legs (deep vein thrombosis, DVT) and lungs (pulmonary embolism, PE) have happened more often in people who are 50 years of age and older and with at least 1 heart disease (cardiovascular) risk factor taking a medicine in the class of medicines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

WHAT'S POSSIBLE

The following photos include computer-generated images of study results. These photos represent pigmentation before treatment with OPZELURA, after 3 months of treatment, and at 6 months of treatment. Repigmentation may continue beyond 6 months.



BEFORE TREATMENT
WITH OPZELURA



VISUALIZATION AFTER
3 MONTHS OF TREATMENT
WITH OPZELURA



VISUALIZATION AT
6 MONTHS OF TREATMENT
WITH OPZELURA

Areas where the hair follicles are sparse, absent, or have turned white may not repigment.

Real person with vitiligo; not an OPZELURA patient. Includes computer-generated images of results. Results not typical. Individual results may vary.

IMPORTANT SAFETY INFORMATION (CONT)

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.

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HOW TO USE OPZELURA

A STEROID-FREE CREAM THAT
CAN FIT INTO YOUR ROUTINE

HOW TO USE

Limit the amount of time you spend in the sunlight. Wear protective clothing when you are in the sun and use broad-spectrum sunscreen.

TWICE A DAY. EVERY DAY.



- Consistently apply OPZELURA two times each day to the affected skin on up to 10% of body surface area (about the size of ten handprints), perhaps as part of your morning and evening routines
- Apply a thin layer, as directed by your healthcare provider
- Wash your hands after applying OPZELURA, unless hands are being treated. If someone else applies OPZELURA, they should wash their hands after applying OPZELURA
- Use OPZELURA as instructed by your healthcare provider



OPZELURA cream can be applied to sensitive areas like around the eyes, mouth, and genitals.*

*OPZELURA is for use on the skin only. **Do not** use in the eyes, mouth, or vagina. **Do not** use more than one 60 gram tube each week.



HOW TO USE OPZELURA

STAYING ON TRACK FOR REPIGMENTATION

While the OPZELURA clinical trial measured repigmentation after 6 months, some patients saw continued progress using OPZELURA beyond 6 months. Remember to stay on track with treatment and keep using OPZELURA as prescribed by your healthcare provider.

IMPORTANT SAFETY INFORMATION (CONT)

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 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.

IMPORTANT SAFETY INFORMATION (CONT)

- 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

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- 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

IMPORTANT SAFETY INFORMATION (CONT)

- 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 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, and 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.

INDICATION AND USAGE

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**I WANT SOME OF MY SKIN
COLOR BACK."**



Opzelura **On Trac™**

THE SUPPORT PROGRAM
THAT'S TRULY THERE FOR YOU



Designed for people with nonsegmental vitiligo who are prescribed OPZELURA, the program connects you with resources and guidance at every step along your way. With OPZELURA On Trac™, know that you'll have resources along your treatment journey with OPZELURA.



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](https://www.opzelura.com) and selecting the patient's condition.

OPZELURA ON TRAC™ SUPPORT INCLUDES:



Get OPZELURA

- Navigate insurance coverage
- Find savings



Start treatment

- Understand how to use OPZELURA
- Learn what to expect



Stay on track

- Get support
- Track your progress over time



SCAN TO LEARN MORE
ABOUT THE OPZELURA
ON TRAC™ PROGRAM

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(ruxolitinib) cream 1.5%

ASK YOUR HEALTHCARE
PROVIDER ABOUT STARTING
YOUR JOURNEY WITH OPZELURA
TODAY. **PURSUE IT.**

LEARN MORE AT
[OPZELURA.COM/VITILIGO](https://www.opzelura.com/vitiligo)

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 **Incyte**
Dermatology

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