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.

**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.

**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 12–13 and the Full Prescribing Information, including Boxed Warning, and Medication Guide for OPZELURA.
Start by reviewing some facts on OPZELURA—the first and only FDA-approved prescription treatment for nonsegmental vitiligo that helps to repigment the skin.

**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.

**LET YOUR TREATMENT JOURNEY WITH OPZELURA BEGIN. TALK TO YOUR HEALTHCARE PROVIDER ABOUT OPZELURA TODAY.**

**A few quick facts on OPZELURA**

- OPZELURA is a **twice-daily topical cream** that was studied in a range of skin tones.

- It targets the **JAK-STAT pathway**. While it is not known if targeting the JAK-STAT pathway leads to repigmentation, it is believed to help reduce the destruction of pigment-producing cells (melanocytes).

- OPZELURA is for use on the skin only on **up to 10% of body surface area (BSA)**.

- It can even be **applied to sensitive areas** like around the eyes (including eyelids), mouth, and genitals. *Do not use in the eyes, mouth, or vagina.*

**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. 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.

Please see additional Important Safety Information on pages 12-13 and the Full Prescribing Information, including Boxed Warning, and Medication Guide for OPZELURA.
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.

Important Safety Information (Cont.)

Causes & triggers

There’s a difference between what fundamentally causes vitiligo and the events that can trigger a spread in depigmentation.

**Causes**

Vitiligo is driven by a process that occurs below the skin’s surface. Here’s a quick look at how this process plays out:

- Vitiligo is thought to be an autoimmune condition.
- With vitiligo, a person’s overactive immune system attacks pigment-producing cells in the skin.
- The loss of pigment-producing cells leads to a loss of the skin’s natural color.

**Triggers**

Vitiligo can manifest without any apparent triggers, but depigmentation can emerge after events such as:

- Emotional or physical stress
- Injury to the skin
- Severe sunburn or sun damage
- Exposure to certain chemicals

Please see additional Important Safety Information on pages 12-13 and the Full Prescribing Information, including Boxed Warning, and Medication Guide for Opzelura.
HOW OPZELURA WORKS

Vitiligo starts below the surface

It’s more than just cosmetic. Vitiligo is 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.

Targeting a key source

OPZELURA is the first and only prescription treatment for nonsegmental vitiligo to address an immune signal known as the JAK-STAT pathway. In people with vitiligo, this pathway is overactive, driving inflammation responsible for the destruction of pigment-producing cells in the skin called melanocytes, leading to a patchy loss of color. Targeting the JAK-STAT pathway is thought to help reduce melanocyte destruction and create an environment where repigmentation can take place over time.

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.

**FOR ILLUSTRATIVE PURPOSES ONLY**

Please see additional Important Safety Information on pages 12-13 and the Full Prescribing Information, including Boxed Warning, and Medication Guide for OPZELURA.
OPZELURA RESULTS

PROVEN REPIGMENTATION

How OPZELURA was studied

OPZELURA was studied in two clinical trials for 6 months. Participants included 674 people (450 receiving OPZELURA, 224 receiving a vehicle cream with no active ingredient) aged 12 and older with nonsegmental vitiligo. 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. The mean time since diagnosis of nonsegmental vitiligo was 14.8 years prior to subjects enrolling in the trials. Phototherapy was not permitted during the trial. In clinical trials, OPZELURA was proven to help restore some skin color over time. Individual results may vary.

Facial Vitiligo: Getting Some Color Back

In two clinical studies...

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.

Specifically, across two 6-month studies, a similar proportion (15.5% and 15.4%) of those using OPZELURA achieved a 90% improvement to vitiligo areas on the face compared with 2.2% and 1.9%, respectively, of those using a non-medicated cream.

FACIAL VITILIGO: GETTING SOME COLOR BACK

In two clinical studies...

About one third of participants saw 75% improvement in a score that measured vitiligo areas on the face after 6 months.

About one sixth of participants saw 90% improvement in a score that measured vitiligo areas on the face after 6 months.

Other findings...

Specifically, across two 6-month studies, a similar proportion (51.5% and 51.4%) of those using OPZELURA achieved a 50% improvement to vitiligo areas on the face compared with 17.2% and 23.4%, respectively, of those using a non-medicated cream.

OPZELURA Snapshots

The following photos represent two patients’ results before treatment with OPZELURA, after 3 months of treatment, and after 6 months of treatment. Individual results may vary, and satisfactory repigmentation may sometimes take longer than 6 months.

Important Safety Information (Cont.)

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

Please see additional Important Safety Information on pages 12–13 and the Full Prescribing Information, including Boxed Warning, and Medication Guide for OPZELURA.
IMPORTANT SAFETY INFORMATION (CONT.)

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
- fever.

In both clinical studies, after the first 6 months, participants were given the option of continuing on OPZELURA for an additional 6 months. Also, any participants who had been part of the inactive vehicle cream participant group for the 6-month study period were given the opportunity to start on OPZELURA for a 6-month period. Ask your healthcare provider about the long-term results of OPZELURA.

Across two 6-month studies, a similar proportion (20.6% and 26.1%) of those using OPZELURA achieved a 50% improvement to vitiligo areas in the total body (including the face) compared with 4.9% and 11.3% of those using a non-medicated cream.

These photos represent one patient’s results and are not typical. Areas of the body with a lower concentration of hair follicles may repigment more slowly than others. Not all vitiligo areas included in the total body measurement are represented in the photos below.

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

BEYOND 6 MONTHS

In both clinical studies, after the first 6 months, participants were given the option of continuing on OPZELURA for an additional 6 months. Also, any participants who had been part of the inactive vehicle cream participant group for the 6-month study period were given the opportunity to start on OPZELURA for a 6-month period. Ask your healthcare provider about the long-term results of OPZELURA.

IMPORTANT SAFETY INFORMATION (CONT.)

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 1-855-463-3483.

Please see additional Important Safety Information on pages 12-13 and the Full Prescribing Information, including Boxed Warning, and Medication Guide for OPZELURA.
**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.

- **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 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 health 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 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 red or white 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 the 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.

- 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.

Please see the accompanying Full Prescribing Information, including boxed warning, and Medication Guide for OPZELURA.
Repigmentation can be possible with OPZELURA, but it does take time. If you don’t see a meaningful difference after the first 6 months, reach out to your doctor for support.

OPZELURA cream can also be applied to sensitive areas like around the eyes (including eyelids), mouth, and genitals.*

How much to use

Apply a thin layer of OPZELURA twice daily on your body’s affected areas—up to 10% of your body surface area based on the direction from your healthcare provider. That’s about the size of ten handprints. Do not use more than one 60 gram tube each week. If you’re still unsure, ask your healthcare provider for guidance on how much to use and where you should apply OPZELURA.

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

IMPORTANT SAFETY INFORMATION (CONT.)

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.

IMPORTANT SAFETY INFORMATION (CONT.)

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 on pages 12-13 and the Full Prescribing Information, including Boxed Warning, and Medication Guide for OPZELURA.
A REFRESHING CHAT WITH YOUR HEALTHCARE PROVIDER

Start a new chapter in your vitiligo story by talking with a healthcare provider. If you haven’t found a dermatologist, or can’t find the words, these tips can help you get the conversation going.

If you’re not sure who to consult

- **Start with trust.** Connect with your most trusted healthcare provider—the one who’s really got your back—and see which dermatologist they’d recommend.
- **Look for a specialist.** To map out a vitiligo treatment plan, finding a healthcare provider who specializes in skin conditions could be a great place to start.
- **Do a little homework.** While awaiting your appointment, start keeping track of your condition and preparing for a productive first visit.

If you’re not sure what to say

Before meeting with your healthcare provider, take some time to document topics or questions you’ll want to discuss.

- **Review your history** with vitiligo (for example: where spots have appeared, how quickly they grow or change, what treatments you’ve tried).
- **Describe what you want** in a vitiligo treatment.
- **If your healthcare provider prescribes OPZELURA,** make note of their instructions for use (where to apply on skin, how much to use in each application).

CAREGIVER SUPPORT

If you’re caring for someone with vitiligo, **reassure them** with your support. Align on their goals before the appointment and be ready to help them through the conversation. You can also **take notes** to review together afterward.

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.

**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 12-13 and the Full Prescribing Information, including Boxed Warning, and Medication Guide for OPZELURA.
FINANCIAL ASSISTANCE AND SAVINGS

To learn more about IncyteCARES and how you can enroll in the program, visit IncyteCARES.com or call 1-800-583-6964, Monday through Friday, 8 AM-8 PM ET.

Support for eligible patients who are uninsured and patients with Medicare Part D who cannot afford their copay may be available through the IncyteCARES for OPZELURA Patient Assistance Program.

The OPZELURA Copay Savings Program

Eligible* patients with commercial insurance may pay as little as $10 per tube for OPZELURA.

Through the OPZELURA Copay Savings Program, you may be able to pay as little as $10 per tube. There are 3 ways to get a card—download it, send it to your email, or get it in a text!

GET A COPAY SAVINGS CARD

In a few steps, you can see if you qualify for OPZELURA Copay Savings.

ACTIVATE YOUR COPAY SAVINGS CARD

Already have your card? If you received a copay savings card from your provider, be sure to check your eligibility so you can activate it before filling your prescription.

GET A COPAY SAVINGS CARD THROUGH TEXT

Always on the go? You can opt to get a copay savings card in a text message.

GET STARTED

Learn more at opzelura.com/vitiligosavings.

*Eligibility required. For use only with commercial prescription insurance. The card may not be used if you are enrolled in a government-funded prescription insurance program or if you pay cash for your prescription. Individual out-of-pocket cost may vary. A maximum benefit 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 your condition.
**TERMS AND CONDITIONS**

Copay Savings Card for OPZELURA Terms and Conditions

By using the copay savings card for OPZELURA, you acknowledge that you currently meet the eligibility criteria and will comply with the Terms and Conditions described below:

- You are not eligible to use this copay savings card if you are enrolled in a state or federally funded prescription insurance program, including, but not limited to, Medicare, Medicaid, TRICARE, Veterans Affairs health care, a state prescription drug assistance program, or the Government Health Insurance Plan available in Puerto Rico (formerly known as “La Reforma de Salud”)
- You must have commercial insurance. Offer is not valid for cash-paying patients
- By using this copay savings card at participating pharmacies, eligible patients with commercial prescription drug insurance coverage for OPZELURA may pay as little as $10 per tube
- Individual out-of-pocket cost may vary based on the price at the pharmacy
- The maximum benefit per tube is capped and a maximum applies per calendar year. For the specific dollar amounts visit opzelura.com
- You agree that neither you nor your guardian, pharmacist, or doctor will seek any third-party reimbursement for the value of the copay savings you receive under this offer
- You are responsible for reporting use of the copay savings card to any commercial insurer, health plan, or other third party that pays for or reimburses any part of the prescription filled using the copay savings card, as may be required. You should not use the copay savings card if your insurer or health plan prohibits use of manufacturer copay cards
- This copay savings card is not valid where prohibited by law
- This copay savings card cannot be combined with any other savings, free trial, or similar offer for the specified prescription
- This copay savings card will be accepted only at participating pharmacies
- This copay savings card is not health insurance
- Offer good only in the U.S. and Puerto Rico
- The copay savings card benefit may not be redeemed more than once per 25 days per patient
- Offer valid only for an FDA-approved use
- No other purchase is necessary
- Data related to your redemption of the copay savings card may be collected, analyzed, and shared with Incyte or its affiliates for market research and other purposes related to assessing Incyte’s programs. Data shared will be aggregated and de-identified; it will not identify you
- Additional Terms and Conditions apply, available at opzelura.com/vitiligosavings

---

**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. 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 12-13 and the Full Prescribing Information, including Boxed Warning, and Medication Guide for OPZELURA.
NOTES
Any questions or thoughts for your healthcare provider?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
OPZELURA IS HERE
Ask your healthcare provider about starting your journey with OPZELURA today.

LEARN MORE AT OPZELURA.COM/VITILIGO

Please see important Safety Information on pages 12-13 and the Full Prescribing Information, including Boxed Warning, and Medication Guide for OPZELURA.

OPZELURA is a trademark of Incyte. Incyte and the Incyte logo are registered trademarks of Incyte. © 2022, Incyte Corporation. MAT-OPZ-01025 09/22