# PREPARE FOR YOUR APPOINTMENT



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.

You may be ready to talk to your healthcare provider about pursuing the potential for repigmentation with OPZELURA, but a little preparation can help make the most of your visit.

- Take a few minutes to complete the Vitiligo Discussion Guide\* below, a survey that can help you identify and share your experiences with vitiligo.
- 2. After completing the survey, be sure to review the useful tips and information at the end of this document.
- **3.** Bring this print-out to your appointment.

\*Please note that the Vitiligo Discussion Guide is not an official tool used to measure vitiligo severity or burden. Follow guidance from your healthcare provider.

#### VITILIGO DISCUSSION GUIDE:

1. How long have you been living with nonsegmental vitiligo?

Less	than 1 ye	ar 1	to 5 years	6	More tha	n 5 years	S			
<b>2.</b> How r	nuch doe	s your vitili	go bothe	r you?						
0 No bothei	ot	2	3	4	5	6	7	8	9	<b>10</b> Extremely bothersome

**3.** Estimate how much of your body is affected by vitiligo. Use the area of the palm of your hand, with your fingers together and thumb to the side, to equal approximately 1% of your body. Consult your healthcare provider with any questions on how to measure the affected areas of your body.

Less than 1% 1-5% 5-10% More than 10%

#### **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.

Please see additional Important Safety Information for OPZELURA throughout this document.



#### 4. Rank each area of your body based on your desire to repigment.

	High	Medium	Low	N/A		
Face						
Head and neck (including scalp)	)					
Torso (including genital area)						
Arms (including underarms)						
Hands						
Legs (including buttocks)						
Feet						
5. Check what is most important <i>Please check all that apply.</i>	to you about OPZI	ELURA.				
FDA-approved Steroid	I-free A topi	cal cream	Repigmentatio	on results*		
A monotherapy (a treatment that can be used on its own) Affordability/Cost						
Studied across a range of ski *After 6 months with OPZELURA: 30% saw		nent to vitiligo on the	e face vs 13% using p	olacebo.		
6. How soon would you expect to Be sure to discuss your expect						
Within 3 months Withir	n 6 months ۱	Vithin 1 year	Within 2 years	s Not sure		

#### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

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



#### WHAT TO BRING TO YOUR APPOINTMENT:

- A list of other medications you are currently using or have used in the past
- △ A list of skincare products you might be using
- Your insurance card
- A Photos of the areas you're hoping to repigment

#### SOME QUESTIONS WORTH ASKING:

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How long should I expect it to take for my skin to repigment?

Will certain areas of my body repigment faster than others?

Is OPZELURA safe for me to use long-term?

Should I apply sunscreen or other hygiene products before or after I apply OPZELURA?

Are there areas I should avoid when applying OPZELURA?

## **COPAY INFORMATION:**

#### **PAY AS LITTLE AS \$0 PER TUBE FOR OPZELURA**

For more information and to **see if you're eligible\***, visit: <u>opzelura.com/vitiligo/copay-savings-program</u>

\*Eligibility required. For use only with commercial prescription insurance. The card may not be used if the patient is enrolled in a government-funded insurance program or if they pay cash for their prescription. Individual outof-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** and selecting the patient's condition.



#### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

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



### TIPS FOR TREATMENT:

Repigmentation takes time. Nonsegmental vitiligo is a life-long condition. **Long term, twice-daily** use of OPZELURA may be required to restore and maintain pigmentation.

- Be sure to use OPZELURA exactly as your healthcare provider prescribes it\*
- Take weekly photos of your treatment areas to track your progress
- Sollow up with your healthcare provider regularly
- If treatment is stopped, depigmentation can occur over time

NDC 50881-007-05

at Use Only

Opzelura<sup>\*</sup> (ruxolitinib) cream 1.5<sup>%</sup>

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#### IF YOUR HEALTHCARE PROVIDER PRESCRIBES OPZELURA TO YOU, MAKE SURE TO ASK FOR THE GETTING STARTED KIT

Get downloadable tools and other resources to help your journey at <u>opzelura.com/vitiligo/staying-on-track</u>

#### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

- 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 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 <u>1-855-463-3463</u> or <u>www.opzelura.pregnancy.incyte.com</u>.
- 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.

#### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

- 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 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 <u>1-800-FDA-1088</u>. You may also report side effects to Incyte Corporation at <u>1-855-463-3463</u>.

Please see the <u>Full Prescribing Information</u>, including Boxed Warning, and <u>Medication Guide</u> for OPZELURA.



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