

Name: _____

Date of First Application: _____

 **Opzelura[®]**
(ruxolitinib) cream 1.5%

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.

CONNECT WITH YOUR TREATMENT STORY



INSTRUCTIONS

Use this log to check in with yourself at each new month of treatment (every four weeks) and capture your observations, your impressions and any pigment changes while using OPZELURA from the past month. This record just might come in handy at your next healthcare appointment.

Remember to apply a thin layer of OPZELURA twice daily to affected areas on up to 10% of body surface area (BSA) as directed by your healthcare provider. At your next appointment, ask your healthcare provider about refilling OPZELURA. OPZELURA is for use on the skin only. Do not use OPZELURA in your eyes, mouth, or vagina. Do not use more than one 60 gram tube each week.

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



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 8–9, and the Full Prescribing Information, including Boxed Warning, and Medication Guide for OPZELURA.



START – MONTH 1

YOUR
FIRST FOUR
WEEKS



STARTING A NEW HABIT

When treating your nonsegmental vitiligo with OPZELURA, it's important to follow the application instructions—consistently. And as with building any new habit, the first few months are your best shot at turning a new routine into something that feels like second nature. Get started by planning out when and where you'll typically apply OPZELURA cream according to your healthcare provider's instructions.

Each morning, I will apply OPZELURA cream _____ in _____
(Time – at 8:00 AM, after my shower, etc.)
(Location – primary bathroom, etc.)

Each evening, I will apply OPZELURA cream for a second time
_____ in _____.
(Time – at 8:00 PM, before bed, etc.) (Location – primary bathroom, etc.)

How are you feeling about getting started with OPZELURA? (Circle one)



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SATISFIED



EXCITED

Why? _____



Once you've decided when you'll be applying your twice-daily treatments, try using your phone's calendar, reminder, or alarm apps to set recurring notifications to help you to stay on track. And while you're at it, you can also set a separate reminder to check in with your journal once every four weeks.

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.

Please see additional Important Safety Information on pages 8–9, and the Full Prescribing Information, including Boxed Warning, and Medication Guide for OPZELURA.

~**MONTH 2**

WEEKS 5
THROUGH 8



KEEPING IT UP






If keeping up with the routine still feels like a challenge, you're not alone. Most people need more than just four weeks for a new routine to start feeling automatic. But stick with it! It can take time for skin to introduce new pigment-producing cells, and good habits can take time to get established. Now is a good time to speak to your pharmacist about setting up auto-refill.

Have you been applying OPZELURA twice daily for the last four weeks? YES OR NO

No judgment here, but if you missed any applications, how many? _____

What part of daily life seems to have gotten in the way? _____

How have you been feeling about your treatment experience over the past month? (Circle one)

DISCOURAGED FRUSTRATED SO-SO SATISFIED EXCITED

Why? _____

Any notes or questions for your healthcare provider? _____



By taking monthly photos of your skin, you can keep a visual record of any progress with OPZELURA. Now would be a great time to start! Try setting a new monthly reminder (every four weeks) to snap a few photos of the areas you're treating with OPZELURA.

To allow a clear comparison between these photos, try to capture all of them under similar conditions. Choose an area of your home without direct sunlight (like a windowless room) to avoid glare and other lighting inconsistencies. And, to get a clear image of your full face, take off your glasses and move any hair that's covering your forehead.

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.

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~**MONTH 3**

WEEKS 9
THROUGH 12



UNDERSTANDING THE PROCESS

OPZELURA is the first and only FDA-approved prescription treatment for nonsegmental vitiligo that helps to repigment skin in patients 12 and older. Remember that the body's process of repigmentation can take a number of months to show results. So be sure to follow your healthcare provider's instructions, and keep at it as directed. To make sure your refills are always ready to help maintain regular applications, speak with your pharmacist!

Have you been applying OPZELURA twice daily for the last four weeks?

YES

OR

NO

Have you taken your monthly progress photo?

YES

OR

NO

No judgment here, but if you missed any applications, how many?

What part of daily life seems to have gotten in the way?

How have you been feeling about your treatment experience over the past month? (Circle one)



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Why? _____

Any notes or questions for your healthcare provider? _____

Talk to your healthcare provider ASAP if you aren't seeing the results you were expecting. The sooner you speak to them, the sooner they could help!



Way to go! You just passed a milestone in the journey of habit-formation. Research has shown that a new daily behavior—like applying OPZELURA cream in the morning and night—tends to start feeling automatic once you've stuck with it for ten weeks.

IMPORTANT SAFETY INFORMATION (CONT.)

Cancer and immune system problems (cont.): 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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~**MONTH 4**

WEEKS 13
THROUGH 16



LOOKING FOR SIGNS

If you're keeping an eye out for any signs of progress, it can help to understand how the skin creates pigment. Skin color is made by pigment-producing cells (melanocytes) that mainly come from the hair follicles. So, if the skin begins to repigment, its first freckles of pigment are likely to appear in the areas around the hairs of depigmented skin. Remember, repigmentation is a slow process that can take months, depending on where your nonsegmental vitiligo is located.

Have you been applying OPZELURA twice daily for the last four weeks?

YES

OR

NO

Have you taken your monthly progress photo?

YES

OR

NO

Have you checked for repigmentation compared to your earliest progress photo?

YES

OR

NO

No judgment here, but if you missed any applications, how many? _____

What part of daily life seems to have gotten in the way? _____

How have you been feeling about your treatment experience over the past month? (Circle one)



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Why? _____

Any notes or questions for your healthcare provider? _____

Those monthly progress photos might start coming in handy. Compare your earliest progress photo with where you are right now. Do you see a difference? If not, don't worry! Sometimes it takes longer for visible results to appear. Continue to talk with your healthcare provider about your treatment.



IMPORTANT SAFETY INFORMATION (CONT.)

Cancer and immune system problems (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.

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~**MONTH 5**

WEEKS 17
THROUGH 20

STAYING THE COURSE

You've made it so far! Even though applying OPZELURA twice daily might be a habit by now, it's still a major commitment. Now is a good time to remember that the process of restoring some of that pigment could take many months. Continue to work with your healthcare provider and stick with your treatment plan.

Have you been applying OPZELURA twice daily for the last four weeks?

YES

OR

NO

Have you taken your monthly progress photo?

YES

OR

NO

Have you checked for repigmentation compared to your earliest progress photo?

YES

OR

NO

No judgment here, but if you missed any applications, how many? _____

What part of daily life seems to have gotten in the way? _____

How have you been feeling about your treatment experience over the past month? (Circle one)



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Why? _____

Any notes or questions for your healthcare provider? _____



Try to keep time in perspective. In two studies, it took 6 months for 29.9% of those using OPZELURA to achieve a 75% improvement to vitiligo areas on the face, while 7.5% and 12.9% of those not using OPZELURA achieved a 75% improvement in 6 months.

IMPORTANT SAFETY INFORMATION (CONT.)

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.

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~**MONTH 6**

WEEKS 21
THROUGH 24



MOVING FORWARD

Wow—you've come a long way to get here! 20 weeks. 140 days. 280 treatment applications. It's a pretty big deal, sticking to your commitment for as long as you have. And, if you're happy with where the results are heading, this may not have to be the end of your journey. Talk to your healthcare provider to see if continued use of OPZELURA is right for you.

Have you been applying OPZELURA twice daily for the last four weeks?

YES

OR

NO

Have you taken your monthly progress photo?

YES

OR

NO

Have you checked for repigmentation compared to your earliest progress photo?

YES

OR

NO

No judgment here, but if you missed any applications, how many? _____

What part of daily life seems to have gotten in the way? _____

How have you been feeling about your treatment experience over the past month? (Circle one)



DISCOURAGED



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SO-SO



SATISFIED



EXCITED

Why? _____

Any notes or questions for your healthcare provider? _____

When was the last time you spoke to your healthcare provider? 24 weeks is around when patients really start to see some notable progress. If you have any concerns about your progress, talk to your healthcare provider ASAP!

Consider bringing this journal and your progress photos along to help guide that discussion. Tell your healthcare provider if your treated skin does not improve within 24 weeks of treatment.



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. This may be life-threatening.

Please see additional Important Safety Information on pages 8–9, and the Full Prescribing Information, including Boxed Warning, and Medication Guide for OPZELURA.

IMPORTANT SAFETY INFORMATION

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

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.

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 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
- 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 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
 - 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.

Please see the accompanying Full Prescribing Information, including Boxed Warning, and Medication Guide for OPZELURA.

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