

ITCH-SCRATCH-INFLAMMATION
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— THE ONE-OF-A-KIND —
TOPICAL JAK INHIBITOR

NEW for uncontrolled, mild to moderate atopic dermatitis (AD)
in non-immunocompromised patients aged ≥ 12 years¹

 **Opzelura™**
(ruxolitinib) cream 1.5%

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

Patients treated with oral Janus kinase inhibitors for inflammatory conditions are at risk for developing serious infections that may lead to hospitalization or death. Reported infections include:

- Active tuberculosis, which may present with pulmonary or extrapulmonary disease.
- Invasive fungal infections, including candidiasis and pneumocystosis.
- Bacterial, viral, and other infections due to opportunistic pathogens.

Avoid use of OPZELURA in patients with an active, serious infection, including localized infections. If a serious infection develops, interrupt OPZELURA until the infection is controlled. Carefully consider the benefits and risks of treatment prior to initiating OPZELURA in patients with chronic or recurrent infection. Closely monitor patients for the development of signs and symptoms of infection during and after treatment with OPZELURA.

No cases of active tuberculosis (TB) were reported in clinical trials with OPZELURA. Cases of active TB were reported in clinical trials of oral Janus kinase inhibitors used to treat inflammatory conditions. Consider evaluating patients for latent and active TB infection prior to administration of OPZELURA. During OPZELURA use, monitor patients for the development of signs and symptoms of TB.

Please see Important Safety Information throughout and [Full Prescribing Information](#) and [Medication Guide](#).

IMPORTANT SAFETY INFORMATION (continued)

SERIOUS INFECTIONS (continued)

Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical trials with Janus kinase inhibitors used to treat inflammatory conditions including OPZELURA. If a patient develops herpes zoster, consider interrupting OPZELURA treatment until the episode resolves.

Hepatitis B viral load (HBV-DNA titer) increases, with or without associated elevations in alanine aminotransferase and aspartate aminotransferase, have been reported in patients with chronic HBV infections taking oral ruxolitinib. OPZELURA initiation is not recommended in patients with active hepatitis B or hepatitis C.

MORTALITY

Higher rate of all-cause mortality, including sudden cardiovascular death, has been observed in patients treated with oral Janus kinase inhibitors for inflammatory conditions.

MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with Janus kinase inhibitors for inflammatory conditions. Patients who are current or past smokers are at additional increased risk. Non-melanoma skin cancers, including basal cell and squamous cell carcinoma, have occurred in patients treated with OPZELURA. Perform periodic skin examinations during OPZELURA treatment and following treatment as appropriate.

MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE)

Higher rate of MACE (including cardiovascular death, myocardial infarction, and stroke) has been observed in patients treated with Janus kinase inhibitors for inflammatory conditions. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with OPZELURA, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if these symptoms occur.

THROMBOSIS

Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis has been observed in patients treated with oral Janus kinase inhibitors for inflammatory conditions. Many of these adverse reactions were serious and some resulted in death. Patients with symptoms of thrombosis should be promptly evaluated.

Thromboembolic events were observed in clinical trials with OPZELURA. There was no clear relationship between platelet count elevations and thrombotic events. OPZELURA should be used with caution in patients who may be at increased risk of thrombosis.

Thrombocytopenia, Anemia and Neutropenia

Thrombocytopenia, anemia and neutropenia were reported in the clinical trials with OPZELURA. Consider the benefits and risks for individual patients who have a known history of these events prior to initiating therapy with OPZELURA. Perform CBC monitoring as clinically indicated. If signs and/or symptoms of clinically significant thrombocytopenia, anemia, and neutropenia occur, patients should discontinue OPZELURA.

Lipid Elevations

Treatment with oral ruxolitinib has been associated with increases in lipid parameters including total cholesterol, low-density lipoprotein (LDL) cholesterol, and triglycerides.

Please see Important Safety Information throughout and [Full Prescribing Information](#) and [Medication Guide](#).

— THE ONE-OF-A-KIND — TOPICAL JAK INHIBITOR

>50%

A Clear Difference

of patients achieved clear or almost clear skin (IGA 0/1) with ≥ 2 -point improvement from baseline at week 8*
(53.8% vs 15.1% and 51.3% vs 7.6% vehicle[†]; $P < 0.0001$)^{1,2}

>50%

Meaningful Itch Relief

of patients achieved a clinically meaningful improvement in itch (Itch NRS4[‡]) at week 8
(52.2% vs 15.4% and 50.7% vs 16.3% vehicle[†]; $P < 0.0001$)^{1,2}
– Itch NRS4 response seen as early as day 3
(18.4% vs 4.2% vehicle and 13.2% vs 0% vehicle[†])³

>60%

Significant EASI Improvement

of patients achieved a $\geq 75\%$ improvement in lesion extent and severity (EASI-75[§]) at week 8
(62.1% vs 24.6% and 61.8% vs 14.4% vehicle[†]; $P < 0.0001$)²
Mild defined as EASI score 1.1–7.0.⁴
In TRuE-AD1 and TRuE-AD2, respectively, 46% and 50% of patients on OPZELURA vs 56% and 44% of patients on vehicle had a baseline EASI score of 1.1–7.0.³



Safety and Tolerability Results

The most common adverse reactions ($\geq 1\%$) were nasopharyngitis, diarrhea, bronchitis, ear infection, eosinophil count increased, urticaria, folliculitis, tonsillitis, and rhinorrhea. See Important Safety Information throughout¹

Choose **OPZELURA**—powerful itch and inflammation relief¹

OPZELURA was studied in 1249 adult and adolescent patients ≥ 12 years of age in 2 identically designed double-blind, randomized, vehicle-controlled trials (TRuE-AD1 and TRuE-AD2). In both studies, patients had an affected BSA of 3%-20% and an IGA score of 2 or 3 on a severity scale of 0-4. Patients were randomized to monotherapy with OPZELURA or vehicle BID for 8 weeks.^{1,2}

*Measured by IGA-TS, defined as achievement of clear (IGA 0) or almost clear (IGA 1) skin with at least a 2-point improvement from baseline.¹

[†]In TRuE-AD1 and TRuE-AD2, respectively.^{1,2}

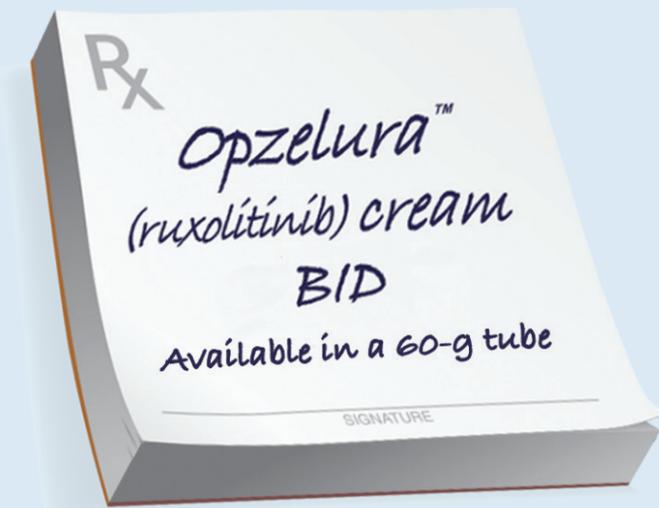
[‡]Itch NRS4 is defined as the achievement of at least a 4-point improvement in daily itch on a 0- to 10-point scale, considered a clinically meaningful response; patients in the analysis had an NRS score of ≥ 4 at baseline.^{1,2}

[§]EASI-75 is defined as the achievement of at least 75% improvement in EASI score from baseline.¹

BID=twice daily; BSA=body surface area; EASI=Eczema Area and Severity Index; IGA=Investigator's Global Assessment; IGA-TS=Investigator's Global Assessment Treatment Success; JAK=Janus kinase; NRS=numeric rating scale.

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(ruxolitinib) cream 1.5%

NONGREASY, NONSTEROIDAL CREAM FORMULATION¹



Can be applied as a thin layer twice daily to affected skin on up to 20% BSA (no more than 60 g per week)¹

Directly applied on AD lesions, including in sensitive skin areas¹

For topical use only. Not for ophthalmic, oral, or intravaginal use. Stop using when signs and symptoms (eg, itch, rash, and redness) of AD resolve. If signs and symptoms do not improve within 8 weeks, patients should be reexamined by their healthcare provider.¹

WITH COPAY SAVINGS CARD, ELIGIBLE* PATIENTS MAY PAY AS LITTLE AS

\$10
PER TUBE

*Eligibility required. Individual savings limited to \$2,076.50/tube, \$10,000 per year. For use only with commercial 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. Must be used for an FDA-approved indication. **Additional Terms and Conditions apply.**

IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions

The most common adverse reactions ($\geq 1\%$) are nasopharyngitis (3%), diarrhea (1%), bronchitis (1%), ear infection (1%), eosinophil count increased (1%), urticaria (1%), folliculitis (1%), tonsillitis (1%), and rhinorrhea (1%).

Pregnancy

There will be a pregnancy registry that monitors pregnancy outcomes in pregnant persons exposed to OPZELURA during pregnancy. Pregnant persons exposed to OPZELURA and healthcare providers should report OPZELURA exposure by calling 855-4MEDINFO or 855-463-3463.

Lactation

Advise women not to breastfeed during treatment with OPZELURA and for four weeks after the last dose (approximately 5 elimination half-lives).

References: **1.** Opzelura. Prescribing Information. Incyte Corporation; 2021. **2.** Papp K, Szepietowski JC, Kircik L, et al. Efficacy and safety of ruxolitinib cream for the treatment of atopic dermatitis: results from 2 phase 3, randomized, double-blind studies. *J Am Acad Dermatol*. Published online May 3, 2021. doi:10.1016/j.jaad.2021.04.085. **3.** Data on file. Incyte Corporation. 2021. **4.** Leshem YA, Hajar T, Hanifin JM, Simpson EL. What the Eczema Area and Severity Index score tells us about the severity of atopic dermatitis: an interpretability study. *Br J Dermatol*. 2015;172(5):1353-1357.

INDICATION

OPZELURA is indicated for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

Limitation of Use:

Use of OPZELURA in combination with therapeutic biologics, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine is not recommended.

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Visit OpzeluraHCP.com to learn more

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