PRESCRIBING INFORMATION

Opzelura (ruxolitinib) 15 mg/g cream

Indication: Opzelura is indicated for the treatment of non-segmental vitiligo with facial involvement in adults and adolescents from 12 years of age.
Active ingredient: One gram of cream contains 15 mg of ruxolitinib (as phosphate).
Dosage and administration: The recommended dose is a thin layer of cream applied twice daily to the depigmented skin areas up to a maximum of 10% of body surface area (BSA), with a minimum of 8 hours between two applications of ruxolitinib cream. 10% BSA represents an area as large as 10 times the palm of one hand with the 5 fingers. Ruxolitinib cream should be used at the smallest skin area necessary.
No more than two tubes of 100 grams a month should be used.
Satisfactory repigmentation may require treatment beyond 24 weeks. If there is less than 25% repigmentation in treated areas at week 52, treatment discontinuation should be considered.
Once satisfactory repigmentation is achieved, treatment in those areas can be stopped. If depigmentation recurs after treatment discontinuation, therapy can be reinitiated on the affected areas.
The cream is for cutaneous use only. Avoid washing treated skin for at least 2 hours after application of ruxolitinib cream. The cream should not be applied to the lips to avoid its ingestion.
Patients should be instructed to wash their hands after applying the cream, unless it is their hands that are being treated. If someone else applies the cream to the patient, they should wash their hands after application.
Contraindications: Hypersensitivity to ruxolitinib or excipients. Pregnancy and breast-feeding.
Warnings and precautions: Non-melanoma skin cancer: A causal relationship to topical ruxolitinib has not been established. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer. Excipients with known effect: Propylene glycol may cause skin irritation. Cetyl alcohol and stearyl alcohol may cause local skin reactions (e.g. contact dermatitis). Parahydroxybenzoates may cause allergic reactions (possibly delayed). Butylated hydroxytoluene may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.
Fertility, pregnancy and breast-feeding: Women of childbearing potential must use effective contraception during treatment and for 4 weeks after discontinuation of treatment. Ruxolitinib is contraindicated during pregnancy and breast-feeding. Discontinue breast-feeding during treatment with ruxolitinib and for 4 weeks following last application. Consult the SmPC for full details.
Undesirable effects: The most common adverse reaction is application site acne.
Quantities and marketing authorisation numbers: 100 g tube. EU/1/23/1726/001-002,
Legal categorisation: POM
Marketing authorisation holder: Incyte Biosciences Distribution B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Netherlands. For further information phone 1800-456-748
Date of preparation: November 2024
Approval Code: IE/OPZL/P/24/0021

Adverse events should be reported.
Reporting forms and information can be found at HPRA Pharmacovigilance: www.hpra.ie
Adverse events should also be reported to Incyte by calling 1800-456-748