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24 April 2025

Opzelura® 15 mg/g cream (ruxolitinib phosphate): Important information regarding presence of particles in Opzelura® cream

Dear Healthcare professional,

The marketing authorisation holder Incyte Biosciences Distribution B.V. (“Incyte”), in agreement with the European Medicines Agency (EMA) and Malta Medicines Authority, would like to inform you of the following:

Summary

Complaints about the presence of small, visible crystal-like particles in Opzelura® (ruxolitinib) cream have been reported. The particles might form out of the active ingredient (ruxolitinib, as the dihydrate).

- While these crystal-like particles may cause some discomfort to patients when they apply the cream, they do not pose any significant safety risk to patients, nor are expected to impact the product’s efficacy.
- Patients should be advised that small, visible crystal-like particles may be present in Opzelura®.
- If a patient observes crystals in Opzelura® cream they should stop treatment with the affected tube, return the tube to the pharmacy where they obtained it and request a replacement tube as soon as possible.
- A pharmacist who receives a tube of Opzelura® containing visible crystal-like particles should contact Incyte’s Medical Information Team at eumedinfo@incyte.com, and Incyte will arrange for a replacement tube to be sent to them, free of charge.

Background on the safety concern

Opzelura® is indicated for the treatment of non-segmental vitiligo with facial involvement in adults and adolescents from 12 years of age.

Quality complaints and non-serious events reporting

Since the availability of Opzelura® in the European Union/EEA in May 2023, the frequency of complaints received regarding the presence of crystal-like particles has ranged from 6 in 10,000 for all distributed batches to an estimated 1 in 10,000 for batches subject to the latest monitoring controls aimed at limiting the distribution of tubes containing crystal-like particles.

From May 2023 until 5 March 2025, the incidence of patient-reported non-serious events after application of the cream due to presence of crystal-like particles has been very rare (< 1/10,000). These events include pain, scratches, paraesthesia or erythema at the application site.

The crystal formation is not expected to result in significant loss of efficacy over a short period of time.

Root Cause

The precise root cause of the crystal formation is not clear. During manufacturing of Opzelura[®], particles might form out of the active ingredient (ruxolitinib phosphate). If formation of ruxolitinib dihydrate takes place, this could present as small particles in the cream.

Measures taken by the marketing authorisation holder Incyte

Incyte has implemented measures including conducting additional testing for crystal formation of every product batch before release to prevent releasing tubes with crystal formations. In addition, Incyte is developing an alternative formulation to prevent the formation of crystals in the cream going forward. Product quality complaints and adverse events will be monitored continuously.

Call for reporting

Healthcare providers and patients are encouraged to report adverse reactions with Opzelura[®] 15 mg/g cream (ruxolitinib phosphate) to eumedinforincyte.com and, in accordance with the national requirements, suspected Adverse Drug Reactions (ADR) (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form. Report forms may be downloaded from www.medicinesauthority.gov.mt/adrportal, and sent by post or email to;

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000

E: postlicensing.medicinesauthority@gov.mt

Please report the product name and batch/Lot number if available as well as other relevant details.

Local contact point:

If you have any questions, please contact Genesis Pharma Cyprus Ltd, tel.: +357 22765715 or at safety.malta@genesispharmagroup.com

Company contact point:

Company	Product Name	Email	Phone
Incyte	Opzelura [®] 15 mg/g cream (ruxolitinib phosphate)	eumedinforincyte.com Safety.Malta@genesispharmagroup.com	+357 22765715 You can also contact us via telephone. Please visit https://incyte.com/contact-us to find your local number.

Yours faithfully,

Post-Licensing Directorate
Medicines Authority

Disclaimer

This Direct Healthcare Professional Communication has been submitted to you on behalf of Incyte Biosciences Distribution B.V. ("Incyte").

The MMA receives the relevant contact details from both the Medical Council and the Pharmacy Council. Should you wish to amend your details including address, you are asked to contact the Medical Council or Pharmacy Council directly, as may apply.