**Package leaflet: Information for the patient**

**Opzelura 15 mg/g cream**
ruxolitinib

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**



## 1. What Opzelura is and what it is used for

Opzelura contains the active substance ruxolitinib. It belongs to a group of medicines called Janus kinase inhibitors.

Opzelura is used on the skin to treat vitiligo with facial involvement in adults and adolescents from 12 years. Vitiligo is an autoimmune disease, where the body's immune system attacks the cells that produce the skin pigment melanin. This causes a loss of melanin, leading to patches of pale pink or white skin. In vitiligo, ruxolitinib reduces the immune system's activity against the melanin-producing cells, allowing the skin to produce pigment and regain its normal colour.

## 2. What you need to know before you use Opzelura

**Do not use Opzelura**
- if you are allergic to ruxolitinib or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or breastfeeding.

**Warnings and precautions**
Talk to your doctor or pharmacist before using Opzelura.

Opzelura is not for use on the lips, in the eyes, mouth or vagina. If cream accidentally gets into these areas, thoroughly wipe off and/or rinse off the cream with water.

**Children under 12 years**
Do not give Opzelura to children younger than 12 years because it has not been studied in this age group.

**Other medicines and Opzelura**
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Using Opzelura at the same time as other medicines on the affected skin is not recommended, as it has not been studied.

After applying Opzelura, wait at least 2 hours before applying other medicines, sunscreen or body creams/oils to the same skin area.

**Pregnancy and breast-feeding**
Opzelura should not be used by pregnant or breast-feeding women as this has not been investigated. If you are a woman of childbearing age, you should use an effective contraception during treatment and during 4 weeks after applying Opzelura for the last time.

It is not known if ruxolitinib passes into breast milk after applying it to the skin. The effects of this medicine in breastfed infants are unknown; therefore, Opzelura should not be used if you are breast-feeding or planning to breastfeed. You may start breast-feeding approximately four weeks after applying Opzelura for the last time.

**Driving and using machines**
Opzelura is unlikely to have an effect on your ability to drive and use machines.

**Opzelura contains propylene glycol, cetyl alcohol, stearyl alcohol, methyl parahydroxybenzoate, propyl parahydroxybenzoate and butylated hydroxytoluene**
- This medicine contains 150 mg propylene glycol (E1520) in each gram of cream, which may cause skin irritation.
- Cetyl alcohol and stearyl alcoholmay cause local skin reactions (e.g. contact dermatitis).
- Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate may cause allergic reactions (possibly delayed).
- Butylated hydroxytoluene (E321) may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

## 3. How to use Opzelura

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Recommended dose**
- Apply a thin layer of cream twice daily to affected areas of your skin. Wait at least 8 hours between applications.
- The cream should not be used on more than 10% (one tenth) of your body. This surface area represents the equivalent to ten times the palm of one hand with the five fingers.

**Method of administration**
- This medicine is for use on the skin only.
- Do not apply to skin surfaces other than the ones instructed by your doctor. The medicine should be used at the smallest skin area necessary.
- Wash your hands after applying this medicine, unless you are treating your hands. If someone applies this medicine to you, they should wash their hands after application.
- Avoid washing treated skin for at least 2 hours after application of Opzelura.

**Duration of use**
Your doctor will decide how long you should use the cream for.
A minimum duration of 6 months is recommended but satisfactory treatment may require over 12 months. If you achieve satisfactory repigmentation of treated areas, consult your doctor to discuss if treatment of those areas could be stopped. Consult your doctor if you experience loss of repigmentation after stopping treatment.

Do not use more than two 100 gram tubes a month.

**If you use more Opzelura than you should**
Wipe off the excess cream if this occurs.

**If you forget to use Opzelura**
If you forget to apply the cream at the scheduled time, do it as soon as you remember, then continue your normal dosing schedule. However, if the next scheduled dose is due within 8 hours, skip the missed dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported with Opzelura:

**Common** (may affect up to 1 in 10 people)
- acne at application site

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the National Reporting System:

**United Kingdom (Great Britain)**
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Opzelura

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the tube and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30 ºC.

Once the tube has been opened, use the cream within 6 months but not after the expiry date.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What Opzelura contains**
- The active substance is ruxolitinib.
  One gram of cream contains 15 mg of ruxolitinib.
- The other ingredients are butylated hydroxytoluene (E321), cetyl alcohol, dimeticone (E900), disodium edetate (E385), glyceryl stearate, paraffin (E905), macrogol, medium chain triglycerides,

methyl parahydroxybenzoate (E218), phenoxyethanol, polysorbate 20 (E432), propylene glycol (E1520), propyl parahydroxybenzoate, purified water, stearyl alcohol, xanthan gum (E415).

See section 2 “Opzelura contains propylene glycol, cetyl alcohol, stearyl alcohol, methyl parahydroxybenzoate, propyl parahydroxybenzoate and butylated hydroxytoluene”.

**What Opzelura looks like and contents of the pack**
Opzelura cream is coloured white to off-white, supplied in a tube containing 100 g cream. There is one tube per carton.

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Detailed information on this medicine is available on the Medicines and Healthcare products Regulatory Agency web site: http://www.mhra.gov.uk.