Package leaflet: Information for the user

Luxera 160 mg/g cream
Methyl aminolevulinate

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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Luxera is and what it is used for

Luxera is used in the treatment of pre-cancerous skin lesions on the face and scalp (known as actinic keratoses), which are areas of the skin that have been damaged by sunlight and become rough and scaly. Having these lesions means that you may be more likely to get skin cancer in the future unless they are treated.

The treatment consists of application of Luxera and daylight exposure. Damaged skin cells absorb methyl aminolevulinate from the cream and are destroyed by light exposure (known as photodynamic therapy). The surrounding healthy skin is not affected.

2. What you need to know before you use Luxera

Do not use Luxera:
- if you are allergic to methyl aminolevulinate or any of the other ingredients of this medicine (listed in section 6). Luxera contains arachis oil (peanut oil): Do not use this product if you are allergic to peanut or soya
- if you have a rare disease called porphyria.

Warnings and precautions
Talk to your doctor before using Luxera:
- if the skin lesions are of certain types (coloured, deep or located on the genitalia)
- if you have 'thick' actinic keratosis

Direct eye contact with Luxera should be avoided. Luxera cream should not be applied to the eyelids and mucous membranes.

The active substance may cause skin allergy which can lead to angioedema. If you experience the following symptoms: swelling of the face, the tongue or the throat; rash, or difficulty in breathing, you should immediately stop taking Luxera and contact a doctor. A more severe skin reaction may occur in case of prolonged application of Luxera.

Sun exposure and UV therapy
As a general precaution, sun exposure on the treated lesion sites and surrounding skin should be avoided for a couple of days following treatment. If you are being treated with artificial light (UV- therapy), this treatment should be stopped before Luxera treatment.

Other medicines and Luxera
Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding
Treatment with Luxera is not recommended during pregnancy.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines
No effects on the ability to drive and use machines are expected.

Luxera contains arachis oil (peanut oil), cetostearyl alcohol and methyl- and propyl parahydroxybenzoate.
If you are allergic to peanut or soya (containing arachis oil), do not use this medicinal product.
Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).
Methyl- and propyl parahydroxybenzoate (E218, E216) may cause allergic reactions (possibly delayed).

3. How to use Luxera

Adults (including the older people)
Considerations before treatment
Luxera can be used if the temperature is suitable to stay comfortably outdoors for 2 hours. The efficacy of the treatment has been shown to be similar whether the treatment is done on a sunny or cloudy day. If the weather is rainy, or is likely to become so, Luxera should not be used.

Preparation of the lesions and application of the cream
An appropriate sunscreen should be applied to all areas, including the treatment areas that will be exposed to daylight before lesion or field preparation. Only the sunscreen that has been recommended specifically by your doctor should be used. Do not use sunscreen with physical filters such as titanium dioxide, zinc oxide as these filters would inhibit absorption of visible light and may impact efficacy. Only sunscreens with chemical filters should be used.

Each skin lesion will be prepared before treatment, by removing scales and crusts and roughening of the skin surface. This preparation helps Luxera and light to get to all parts of the skin lesion.

A thin layer of Luxera is applied on the lesions or fields with a spatula or gloved hand. Direct eye contact with Luxera cream should be avoided.

Illumination using daylight
You should go outside after Luxera application, or at the latest, 30 minutes later and stay for 2 hours in full daylight or, if needed, in a shaded outdoor area. It is recommended not to go indoors during this time period. Make sure the treatment area is continuously exposed to daylight, and not covered by clothes. It is important to follow these instructions to ensure treatment success and avoid pain during daylight exposure. Following the 2-hour exposure period Luxera cream is washed off.

One session of daylight photodynamic therapy should be given to treat mild or moderate actinic keratoses.

Several lesions or fields may be treated during the same therapy session.

Follow up
Your doctor will decide how well each skin lesion has responded after three months. Treatment may be repeated after this period if necessary.

Use in children and adolescents
Treatment with Luxera is not suitable for use in children or adolescents below 18 years of age.

If you stop using Luxera
If the treatment is stopped before the light therapy is started or before the end of the 2 hours daylight exposure, the effectiveness of the treatment might be reduced.

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

4. Possible side effects

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

The side effects below have been reported when using Luxera (methylaminolevulinate with daylight) for the treatment of actinic keratoses, or when using methyl aminolevulinate with red light for the treatment of actinic keratoses and other indications.

Very common (may affect more than 1 in 10 people): skin pain, skin burning sensation, scab, redness of the skin.

Common (may affect up to 1 in 10 people):
- Effects at treatment site: numbness, tingling or prickling sensation, bleeding (can occur following lesion preparation), warm skin, infection, open sores (ulceration), swelling / oedema of the skin, blistering, itching, flaking of the skin, skin weeping.
- Effects away from treatment site: headache, feeling hot.

Uncommon (may affect up to 1 in 100 people):
- Effects at treatment site: skin irritation, hives, rash, areas of paler or darker skin after healing, sensitivity to light, skin discomfort, heat rash.
- Effects away from treatment site: eye swelling, eye pain, nausea, fatigue.

Not known (frequency cannot be estimated from the available data):
- Allergic reaction which can lead to angioedema with the following symptoms: swelling of the face, the tongue or the throat, or difficulty in breathing.
- Eye lid swelling, pustules and eczema (dry flaky skin) on application site and signs of contact allergy.
- Increase of blood pressure may be induced by pain associated with the use of red light.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Luxera

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 carton and tube. The expiry date refers to the last day of that month.
Store in a refrigerator (2°C – 8°C).
Once opened the cream should be used within 3 months.
Do not use this medicine if you notice visible signs of deterioration (e.g. darkening of the colour from pale yellow to brown).

Do not throw away any medicines via wastewater or household waste. Ask you 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 Luxera contains

- The active substance is methyl aminolevulinate 160 mg/g (as hydrochloride).
- The other ingredients are glyceryl monostearate, cetostearyl alcohol, poloxyl 40 stearate, methyl parahydroxy benzoate (E218), propyl parahydroxybenzoate (E216), disodium edetate, glycerol, white soft paraffin, cholesterol, isopropyl myristate, arachis oil (peanut oil), almond oil, oleyl alcohol, purified water.

What Luxera looks like and contents of the pack

The colour of Luxera is cream to pale yellow. The cream is available in tubes containing 2 g cream.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
<[To be completed nationally]>
{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

Manufacturer
Laboratoires GALDERMA
ZI Montdésir
74540 ALBY SUR CHERAN
FRANCE

or

Galderma Laboratorium GmbH, Toulouser Allee 23a
40211 Düsseldorf, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:
SE: Luxera
AT, DE: Luxerm

This leaflet was last revised in 2022-09-12

<**Other sources of information**>
<Detailed information on this medicine is available on the website of {name of MS Agency (link)}>