PATIENT INFORMATION LEAFLET FOR ELOZART

SCHEDULING STATUS

S2

ELOZART cream

Active ingredients:

Each gram contains 20 mg miconazole nitrate and 10 mg hydrocortisone.

Read all of this leaflet carefully before you start using ELOZART.

- Keep this leaflet. You may need to read it again.
- Do not share ELOZART with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or if no improvement is seen after 7 days of application.

What is in this leaflet

1. What ELOZART is and what it is used for.
2. What you need to know before you use ELOZART.
3. How to use ELOZART.
4. Possible side effects.
5. How to store ELOZART.
6. Contents of the pack and other information.

1. What ELOZART is and what it is used for

ELOZART contains miconazole (an antifungal) and hydrocortisone (a mild corticosteroid).

ELOZART cream is used for the treatment of steroid responsive dermatoses (inflammation of the skin) with fungal and bacterial superinfection, e.g. inflammatory, allergic, and pruritic conditions.

Once the inflammatory symptoms have cleared up, treatment may be continued with a miconazole nitrate cream only, if required.

2. What you need to know before you use ELOZART

Do not use ELOZART:

- If you are hypersensitive (allergic) to miconazole, hydrocortisone or any of the other ingredients (see What ELOZART contains).
- If you have tuberculosis of the skin (an infectious disease caused by the bacterium *Mycobacterium tuberculosis*).
- If you have any viral infection (herpes simplex, vaccinia or varicella).
- If you are pregnant, planning to become pregnant, or are breastfeeding your baby. If you become pregnant while using ELOZART cream, contact your doctor immediately (see Pregnancy, breastfeeding and fertility).

Warnings and precautions

Take special care with ELOZART:

- ELOZART cream must be used as directed by your doctor, for external use only.
- Avoid contact with the eyes or area near the eyes.
- ELOZART cream should be used with particular caution if you have facial dermatoses (inflammation of the skin of the face).
- ELOZART cream should only be used for short periods.
- ELOZART cream should not be used in skin folds.
- Take special care if ELOZART cream is to be applied to infants and children.
- If you are taking oral anticoagulant medicines such as warfarin, stop using ELOZART immediately and seek advice from your doctor or pharmacist if you experience unexpected bleeding or bruising, nosebleeds, coughing up blood, blood in the urine, black tarry stools or coffee ground vomit during treatment with ELOZART. Close monitoring of international normalised ratio (INR) is required under the supervision of a health care provider during treatment with ELOZART.

- ELOZART cream contains butylated hydroxyanisole, which may cause local skin reactions such as contact dermatitis, or irritation to the eyes and mucous membranes.
- ELOZART cream contains cetostearyl alcohol and chlorocresol, which may cause local skin reactions.

Other medicines and ELOZART

Always tell your health care provider if you are taking any other medicine. This includes complementary or traditional medicines.

ELOZART cream may interact with the activity of anticoagulant medicines, such as warfarin (used to prevent your blood from clotting) or herbal supplements with blood thinning effects.

Not all medicines which may interact with ELOZART cream are listed in this leaflet. Discuss all the medicines that you have taken recently and are presently taking with your doctor and health care provider.

Pregnancy, breastfeeding and fertility

The use of ELOZART cream during pregnancy is contraindicated.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using ELOZART.

The use of ELOZART cream is not recommended if you are breastfeeding.

There are no clinical studies with ELOZART cream regarding fertility. No effects are anticipated, since systemic exposure following topical application is negligible.

Driving and using machines

ELOZART cream should not cause drowsiness or dizziness. However, make sure you know how you react to ELOZART cream before driving a vehicle, operating machinery, or doing anything else requiring your attention.

3. How to use ELOZART

Always use ELOZART cream exactly as your doctor has instructed you. Consult your doctor or pharmacist if you are unsure.

For external use only.

Apply once or twice daily by rubbing cream gently into the affected area so that it is completely absorbed by the skin. Treatment should continue until all signs of the lesion have disappeared – usually after 2 to 5 weeks. (As a precautionary measure application should continue, depending on severity of infection, for 14 days after the lesion has disappeared to avoid relapse.)

If no improvement is seen after 7 days of application, please consult your doctor.

If you have the impression that the effect of ELOZART cream is too strong or too weak, talk to your doctor or pharmacist.

If you use more ELOZART than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use ELOZART

Apply the missed dose as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not apply a double dose to make up for a missed one.

4. Possible side effects

ELOZART can have side effects. Not all side effects reported for ELOZART cream are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ELOZART cream, please consult your health care provider for advice.

If any of the following happens, stop using ELOZART cream and tell your doctor immediately or go to the casualty department at your nearest hospital:

Skin rash, redness of the skin, difficulty in breathing, diarrhoea, dizziness.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ELOZART. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following side effects:

- skin irritation at the application site
- burning sensation
- itching
- redness of the face
- thinning of the skin, loss of elasticity
- small visible blood vessels under the skin or mucous membranes (creating focal red lesions)
- easy bruising
- infections may become worse or their symptoms may be hidden
- reduced function of the adrenal glands.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ELOZART.

5. How to store ELOZART

- Store at or below 25 °C. Do not refrigerate.
- Keep well closed and protected from light.
- Store all medicine out of reach of children.
- Do not use after the expiry date printed on the label or carton.

- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ELOZART contains

Each gram contains 20 mg miconazole nitrate and 10 mg hydrocortisone.

The other ingredients are butylated hydroxyanisole, cetomacrogol ‘1000’, cetostearyl alcohol, citric acid monohydrate, liquid paraffin, purified water, sodium dihydrogen phosphate, white soft paraffin.

Contains chlorocresol 0,1 % *m/m* as a preservative.

What ELOZART looks like and contents of the pack

A white, smooth, homogeneous cream free from any visible contaminants. Packed in 15 gram or 20 gram white aluminium lacquered tubes with white polypropylene piercing caps, inside a unit carton.

Holder of certificate of registration

LeBasi Pharmaceuticals (Pty) Ltd

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Access to corresponding Professional Information

Request via the email address: info@lebasi.co.za

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