Package leaflet: Information for the patient

Ledaga® 160 micrograms/g gel

Chlormethine

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 Ledaga is and what it is used for

Ledaga contains the active substance chlormethine. This is an anti-cancer medicine used on the skin to treat mycosis fungoidestype cutaneous T-cell lymphoma (MF-type CTCL).

MF-type CTCL is a condition in which certain cells of the body's immune system called T-lymphocytes become cancerous and affect the skin. Chlormethine is a type of anti-cancer medicine called an 'alkylating agent'. It attaches to the DNA of dividing cells, like cancer cells, which stops them from multiplying and growing.
Ledaga is for use in adults only.

2. What you need to know before you use Ledaga

Do not use Ledaga
- if you are allergic (hypersensitive) to chlormethine or any of the other ingredients of this medicine (listed in section 6).

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

- Contact with your eyes must be avoided. Do not apply the medicine near the eyes, to the inside of the nostrils, the inside of the ear or on the lips.
- If Ledaga gets in your eyes, it can cause pain, burning, swelling, redness, sensitivity to light, and blurred vision. It may also cause blindness and severe permanent injury to your eyes. If Ledaga gets in your eyes, rinse your eyes right away for at least 15 minutes with large amounts of water, a solution known as "0.9% sodium chloride solution" or an eye-wash solution, and seek medical assistance (including an eye doctor) as soon as possible.
- If this medicine gets in your mouth or nose, it can cause pain, redness, and ulcers that may be severe. Rinse the affected area right away for at least 15 minutes with large amounts of water, and seek medical assistance as soon as possible.
- This medicine can cause skin reactions, such as inflammation of your skin (redness and swelling), itching, blisters, ulcers and skin infections (see section 4). The risk for inflammation of the skin is increased if you apply Ledaga to your face, genital area, anus or skin folds.
- Tell your doctor if you have ever had an allergic reaction to chlormethine. Contact your doctor or seek immediate medical attention if you experience allergic reactions to Ledaga (see section 4).
- Skin cancers (abnormal growth of the cells in the skin) have been reported after application of chlormethine to the skin, although it is not known whether chlormethine causes this. Your doctor will check your skin for skin cancers during and after your treatment with Ledaga. Tell your doctor if you get any new damaged areas or ulcers on your skin.
- Direct skin contact with Ledaga should be avoided in individuals other than the patient, such as caregivers. Risks of direct skin contact include inflammation of the skin (dermatitis), injury to their eyes, mouth, or nose, and skin cancers. Caregivers who accidentally come into contact with Ledaga must wash the affected area right away for at least 15 minutes. Remove and wash any contaminated clothing. Get medical help right away if Ledaga gets into your eyes, mouth, or nose.

Children and adolescents
Do not give this medicine to children and adolescents under the age of 18 years because the safety and effectiveness have not been established for this age group.

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

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, ask your doctor for advice before taking this medicine.

There is limited experience of chlormethine in pregnant women. Therefore, the use of this medicine is not recommended during pregnancy and in women of childbearing age not using contraception.

It is not known whether Ledaga passes into breast milk, and there may be a risk that the breast-feeding baby is exposed to Ledaga via contact with the mother's skin. Therefore, it is not recommended to breast-feed while taking this medicine. You should talk to your doctor before breast-feeding to determine whether or not it is best to breast-feed or to use Ledaga.

Driving and using machines
This medicine is not expected to have any effect on your ability to drive or to use machines.

Ledaga contains propylene glycol and butylhydroxytoluene
Propylene glycol may cause skin irritation. Butylhydroxytoluene may cause local skin reactions (e.g. contact dermatits), or irritation to the eyes and mucous membranes.

3. How to use Ledaga

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

Ledaga is intended only for use on the skin.

The recommended dose is application as a thin film once a day to the affected areas of the skin. The dose is the same for elderly patients (aged 65 years and older) as for younger adult patients (aged 18 years and older).

Your doctor may stop your treatment if you develop severe inflammation of the skin (i.e., redness and swelling), blisters and ulcers. Your doctor may restart the treatment upon improvement of your symptoms.

Instructions for use:
- Use Ledaga exactly as your doctor or pharmacist tells you.
- Caregivers must wear disposable nitrile gloves when applying this medicine to patients (this is a special type of glove; ask your doctor or pharmacist if you have questions).
- Remove the cap from the tube just before use. Use the cap to pierce the seal.
- Apply Ledaga immediately or within 30 minutes of removing it from the refrigerator.
- Apply a thin layer of this medicine to completely dry skin at least 4 hours before or 30 minutes after showering or washing.
- Apply Ledaga to affected areas of the skin. In case of Ledaga exposure to non-affected areas of the skin, wash the exposed area with soap and water.
- Allow the area to dry for 5 to 10 minutes after applying your medicine and before covering with clothing.
- For patients applying the gel, wash your hands with soap and water immediately after applying.
- For caregivers applying the gel, carefully remove gloves (turning them inside out during the removal to avoid contact with Ledaga) and then wash hands thoroughly with soap and water.
- Ledaga is supplied within a child-resistant transparent, sealable, plastic bag. If it is not, ask your pharmacist.
- With clean hands, place Ledaga back in the box it came in and the box in the plastic bag. Return it to the refrigerator after each use.
- Do not cover the treated area with air- or water-tight bandages after you have applied this medicine.
- Until Ledaga has dried on the skin, avoid contact with an open flame or a lit cigarette. Ledaga contains alcohol and is therefore considered flammable.
- Do not apply moisturisers or any other skin products (including medicines applied to the skin) for 2 hours before or 2 hours after the daily application of Ledaga.
- Keep away from children and contact with food by storing Ledaga in its box and inside the plastic bag.

If you use more Ledaga than you should
Do not apply Ledaga more than once per day. If you apply more than recommended, talk to your doctor.

If you forget to use Ledaga
Do not use a double dose to make up for a forgotten dose. Apply your next dose when it is due.

If you stop using Ledaga
Your doctor will determine how long you should use Ledaga for and when treatment may be stopped. Do not stop using your medicine until your doctor advises you to do so.

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.

STOP taking Ledaga and tell your doctor **immediately** if you experience allergic reactions (hypersensitivity). These reactions may include some or all of the following symptoms:
- Swelling of the lips, face, throat or tongue
- Rash
- Difficulty breathing

Other side effects may include
Tell your doctor or pharmacist as soon as possible if you notice any of the following side effects listed below.

Very common side effects on the treatment area (may affect more than 1 in 10 people):
- Skin inflammation (dermatitis)
- Infections of the skin
- Itching (pruritus)

Common side effects on the treatment area (may affect up to 1 in 10 people):
- Skin ulcers
- Blisters
- Darkening of the skin

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 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 Ledaga

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 label and box after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (+2 °C to +8 °C) at all times, ensuring the tube is in the box inside the child-resistant, transparent, sealable, plastic bag.

Do not use an opened or unopened tube of Ledaga after 60 days of storage in the refrigerator.

Ask your pharmacist how to throw away used nitrile gloves, the plastic bag and the medicine you no longer use. Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment.

6. Contents of the pack and other information

What Ledaga contains
• The active substance is chlormethine. Each gram of gel contains 160 micrograms of chlormethine.
• The other ingredients are: diethylene glycol monoethyl ether, propylene glycol (E 1520), isopropyl alcohol, glycerol (E 422), lactic acid (E 270), hydroxypropylcellulose (E 463), sodium chloride, menthol racemic, disodium edetate, and butylhydroxytoluene (E321). See end of section 2 for further information on propylene glycol and butylhydroxytoluene.

What Ledaga looks like and contents of the pack
Ledaga is a clear, colourless gel.
Each aluminium tube contains 60 grams of gel and has a white screw cap.

Marketing Authorisation Holder and Manufacturer
Helsinn Birex Pharmaceuticals Ltd.
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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