1.3.2 Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

LEDAGA (topical gel)

Chlormethine, 160 microgram per gram

Read all of this leaflet carefully before you start using Ledaga

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- Ledaga has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What Ledaga is and what it is used for

Ledaga contains the active ingredient chlormethine.

Ledaga is an anti-cancer medicine used on the skin to treat mycosis fungoides-type 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 hypersensitive (allergic) to chlormethine or any of the other ingredients of Ledaga;
- if you are pregnant.

Warnings and precautions

Take special care with Ledaga:

Check with your doctor if you:

- have any other medical conditions;
- take medicines for any other conditions.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them.

Children/ and adolescents

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

What should I know while using Ledaga:

Things you should do:

Tell your doctor of any new skin lesions and have regular check-ups for signs and symptoms of skin cancer. Non-melanoma skin cancers have been reported in patients receiving the active ingredient in Ledaga. Skin cancer may occur at multiple areas, including areas not directly treated with Ledaga.

If you are a caregiver, you must avoid direct skin contact with Ledaga.

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.

Remind any doctor, dentist or pharmacist you visit that you are using Ledaga.

Things you should not do:

Do not apply the medicine near the eyes, to the inside of the nostrils, the inside of the ear or on the lips. If this happens, seek medical assistance as soon as possible.

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. 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. **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. **Seek medical assistance as soon as possible.**

Other medicines and Ledaga

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Ledaga.

Ledaga with food and drink and alcohol

Not applicable.

Pregnancy and breastfeeding and fertility

Pregnancy and breastfeeding

Ledaga is not recommended during pregnancy because it may cause foetal harm. Check with your doctor if you are pregnant or intend to become pregnant. There is limited experience of chlormethine in pregnant women.

Ledaga is not recommended during breastfeeding because of the potential for exposure to Ledaga through exposure to the mother's skin and the potential for serious adverse reactions in the breastfed child from chlormethine. Talk to your doctor if you are breastfeeding or intend to breastfeed.

Contraception

Women with reproductive potential and their partners should use a barrier method (eg. condoms or diaphragm) of contraception while using Ledaga to avoid direct exposure of reproductive organs to Ledaga.

Ask your doctor about the need for contraception before you start taking Ledaga.

Driving and using machinery

It is not always possible to predict to what extent Ledaga may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Ledaga affects them.

Ledaga contains propylene glycol and butylhydroxytoluene

If you experience any skin, eye, nose or mouth irritation while using this medicine speak to your doctor. Ledaga contains inactive ingredients propylene glycol and butylhydroxytoluene that may cause skin irritation. In addition, butylhydroxytoluene may also cause irritation to the eyes and mucous membranes (i.e., mouth and nose).

3. How to use Ledaga

Do not share medicines prescribed for you with any other person.

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

The usual dose is:

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

Ledaga is intended only for use on the skin.

When to use Ledaga

The recommended dose of Ledaga is once per day. If you apply more than recommended, talk to your doctor.

You should use Ledaga at least 4 hours before or 30 minutes after showering or washing so that it can work properly.

Follow the instructions provided below and do not stop using Ledaga unless your doctor tells you to. If you stop your treatment with Ledaga, your symptoms may come back.

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.

How to use Ledaga

If you are a caregiver that is applying the gel to a patient, you must wear disposable nitrile gloves when applying this medicine to avoid contact with the medicine (this is a special type of glove; ask your doctor or pharmacist if you are not sure).

Ledaga is supplied inside a child-resistant transparent, sealable, plastic bag. If it is not, ask your pharmacist.

To apply Ledaga, follow these steps:

• Remove Ledaga from the refrigerator. It should be used within 30 minutes.

• Make sure your skin is completely dry. Use Ledaga at least 30 minutes after showering or washing. Do not apply moisturisers or any other skin products (including medicines applied to the skin) for 2 hours before applying Ledaga.

• Remove the cap from the tube. Use the cap to pierce the seal.

• Apply Ledaga to affected areas of the skin and allow to dry for 5 to 10 minutes.

• If Ledaga is applied to non-affected areas of the skin by mistake, wash these areas with soap and water.

After applying Ledaga follow these steps:

• Do not cover the treated area with air-or water-tight bandages after you have applied Ledaga.

• Do not apply moisturisers or any other skin products (including medicines applied to the skin) for 2 hours after applying this medicine.

• Do not allow contact with an open flame or a lit cigarette until Ledaga has dried. Ledaga contains alcohol and is therefore considered flammable.

• If you are a patient who has applied the gel yourself, 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.

• 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.

Keep away from children and contact with food by storing Ledaga in its box and inside the plastic bag.

If you have the impression that the effect of Ledaga is too strong or too weak, tell your doctor or pharmacist.

If you use more Ledaga than you should

In the event of overdosage (if you apply more than recommended), consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use or missed a dose of Ledaga

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Do not use a double dose to make up for forgotten individual doses.

Apply your next dose when it is due.

4. Possible side effects

Ledaga can have side effects.

Not all side effects reported for Ledaga are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Ledaga, please consult your healthcare professional for advice.

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting;
- difficult beathing.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Common side effects (may affect up to 1 in 10 people):

• Skin ulcers;

• blisters;

• darkening of the skin.

Very common side effects (may affect more than 1 in 10 people):

• Skin inflammation;

• infections of the skin;

• itching (pruritus).

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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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 Ledaga.

5. How to store Ledaga

- Store all medicines out of reach of children.
- Store at or between 2 °C to 8 °C (in a refrigerator) at all times, ensuring the tube is in the box inside the child resistant, transparent, sealable, plastic bag.
- Store in the original package.
- Do not use Ledaga (even when unopened) after 60 days of storage in the refrigerator.
- Do not store in a bathroom

- Do not use after the expiry date stated on the label and carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Ask your pharmacist how to throw away used nitrile gloves.

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,
  - isopropyl alcohol,
  - glycerol,
  - lactic acid,
  - hyprolose,
  - sodium chloride,
  - menthol,
  - disodium edetate,
  - 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.

Holder of Certificate of Registration and Manufacturer

Key Oncologics (Pty) Ltd

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South Africa

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website www.sahpra.org.za