

# Ledaga

## Consumer Medicine Information (CMI) summary

The [full CMI on the next page](#) has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using Ledaga?

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).

For more information, see Section [1. Why am I using Ledaga?](#) in the full CMI.

### 2. What should I know before I use Ledaga?

Do not use if you have ever had an allergic reaction to chlormethine or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Ledaga?](#) in the full CMI.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

### 4. How do I use Ledaga?

- The recommended dose is application as a thin film once a day to the affected areas.
- 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). Patients applying the gel themselves do not need to wear gloves but should wash their hands with soap and water immediately after applying.

More instructions can be found in Section [4. How do I use Ledaga?](#) in the full CMI.

### 5. What should I know while using Ledaga?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor or pharmacist you visit that you are using Ledaga.</li><li>• Tell your doctor of any new skin lesions and have regular check-ups for signs and symptoms of skin cancer.</li><li>• If you experience any skin, eye, nose or mouth irritation while using this medicine speak to your doctor.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not apply the medicine near the eyes, to the inside of the nostrils, the inside of the ear or on the lips.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• This medicine is not expected to have any effect on your ability to drive or to use machines.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store this medicine 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.</li><li>• Do not use an opened or unopened tube of Ledaga after 60 days of storage in the refrigerator.</li></ul>

For more information, see Section [5. What should I know while using Ledaga?](#) in the full CMI.

### 6. Are there any side effects?

Very common side effects include skin inflammation, infections of the skin, itching (pruritus) and common side effects include skin ulcers, blisters and darkening of the skin. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# Ledaga

Chlormethine

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Ledaga. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Ledaga.**

### Where to find information in this leaflet:

1. Why am I using Ledaga?
2. What should I know before I use Ledaga?
3. What if I am taking other medicines?
4. How do I use Ledaga?
5. What should I know while using Ledaga?
6. Are there any side effects?
7. Product details

## 1. Why am I using Ledaga?

Ledaga contains the active ingredient chlormethine.

This 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 should I know before I use Ledaga?

### Warnings

Do not use Ledaga if:

- you are allergic (hypersensitive) to chlormethine or any of the other ingredients of this medicine (listed in section 7).

### 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. See additional information under Section 6. Are there any side effects?

### Pregnancy and breastfeeding

Ledaga is not recommended during pregnancy because it may cause fetal 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 breast feeding 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.

### 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.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**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.**

#### **4. How do I 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.

##### **How much to use**

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). Patients applying the gel themselves do not need to wear gloves.

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 this medicine.
- 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 forget to use Ledaga**

Ledaga should be used regularly at the same time each day. If you miss your dose at the usual time, you can take this later in the same day.

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

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

### **If you use too much Ledaga**

If you think that you have applied too much Ledaga, you may need urgent medical attention.

#### **You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

**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.**

### **Driving or using machines**

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

### **Looking after your medicine**

Store this medicine 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.

Store in the original package in order to protect from moisture.

Follow the instructions in the carton on how to take care of your medicine properly.

**Keep it where young children cannot reach it.**

### **When to discard your medicine**

Do not use Ledaga (even when unopened) after 60 days of storage in the refrigerator.

### **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

## **5. What should I know while using Ledaga?**

### **Things you should do**

**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).

**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**

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p>Very common side effects (may affect more than 1 in 10 people):</p> <ul style="list-style-type: none"> <li>• Skin inflammation</li> <li>• Infections of the skin</li> <li>• Itching (pruritus)</li> </ul> <p>Common side effects (may affect up to 1 in 10 people):</p> <ul style="list-style-type: none"> <li>• Skin ulcers</li> <li>• Blisters</li> <li>• Darkening of the skin</li> </ul> <p>The risk for these side effects is increased if you apply Ledaga to your face, genital area, anus or skin folds.</p>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Swelling of the lips, face, throat or tongue</li> <li>• Rash</li> <li>• Difficulty breathing</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side

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

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Ledaga contains

<b>Active ingredient (main ingredient)</b>	<p>Chlormethine</p> <p>Each gram of gel contains 160 micrograms of chlormethine</p>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• diethylene glycol monoethyl ether</li> <li>• propylene glycol</li> <li>• isopropyl alcohol</li> <li>• glycerol</li> <li>• lactic acid</li> <li>• hypolose</li> <li>• sodium chloride</li> <li>• menthol</li> <li>• disodium edetate</li> <li>• butylhydroxytoluene</li> </ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Ledaga looks like

Ledaga is a clear, colourless gel. Each aluminium tube contains 60 grams of gel and has a white screw cap.

(Aust R 338551).

### Who distributes Ledaga

Juniper Biologics Pty Ltd  
 Level 14 Suite 3A16  
 275 Alfred Street  
 North Sydney  
 NSW 2060, Australia

This leaflet was prepared on 20 October 2022.