

UREA 10% LACTIC ACID 5%

Calmurid[®]

10% / 5% W/W CREAM



PACKAGE LEAFLET: INFORMATION FOR THE USER

Calmurid 10%/ 5% w/w Cream

Urea 10% w/w
Lactic Acid 5% w/w

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

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

1. What Calmurid is and what it is used for

- Your doctor or pharmacist has recommended this cream for use as a moisturising cream for the treatment of dry, rough, scaly skin such as eczema and similar conditions.
- The active substances in Calmurid are urea and lactic acid which act as moisturisers. This helps make your skin soft and supple.

2. What you need to know before you use Calmurid

Do not use Calmurid:

- If you are allergic to urea or lactic acid or any of the other ingredients of this medicine (listed in section 6).

Please seek immediate medical attention if you experience symptoms of an allergic reaction. Signs or symptoms of a severe allergic reaction may include a rash, with or without itching, swelling of the face, eyelids or lips and difficulty in breathing.

Warnings and precautions

Talk to your doctor or pharmacist before using Calmurid.

- Avoid contact with the eyes, eyelids, lips and other mucous surfaces. Upon accidental contact, rinse the affected area with clean water.
- Calmurid may cause stinging if applied to damaged skin (raw cracked areas or cracked skin) or sensitive areas of the body such as the mouth or nostrils.
- If you have ever had kidney disease, ask your doctor or pharmacist for advice before taking this medicine.

Other medicines and Calmurid

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

Calmurid might interfere with other medicines applied to the skin such as:

- topical corticosteroids, which are a group of medicines used on the surface of the skin to reduce the redness and itchiness caused by certain skin problems.
- 5-fluorouracil, used to treat skin conditions such as horny growths of the skin (keratoses) and some skin cancers.
- dithranol, which is used to treat psoriasis.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- Do not apply Calmurid Cream to your chest if you are breast-feeding.

3. How to use Calmurid

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

- Calmurid Cream is for EXTERNAL USE ONLY.
- First gently wash and dry the affected areas of your skin.
- Apply a thick layer over the affected areas. Do not rub it in yet.
- Leave it on your skin for 3 to 5 minutes, then rub it in gently.
- Wipe off any excess cream with a tissue (do not wash it off).
- The cream should be used in this way twice a day, or as advised by your doctor, ideally after washing.
- If you need to use Calmurid on your feet, soak them in water for 15 minutes and then dry them with a rough towel before use.
- How long you will have to use this medicine will depend on how quickly your condition improves. Always seek the advice of your doctor or pharmacist.

If you use more Calmurid than you should or accidentally swallow any of the cream

If you use too much Calmurid and stinging occurs, wash the cream off with water.

In the rare event that you accidentally swallow any of this medicine, seek medical advice.

If you forget to use Calmurid

Do not worry if you forget to use your cream at the right time. When you remember, start using the medicine again as you did before.

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

4. Possible side effects

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

Effects on the skin

- Calmurid may cause stinging if applied to raw areas or cracks in the skin or the lips.
- Keep Calmurid away from other sensitive areas of your body.
- If stinging occurs, wash the cream off with water.
- Should stinging be a problem, you can mix it with an equal amount of Aqueous Cream BP (ask your pharmacist for this) for a week, after which it would be alright to use the cream on its own again, but you must consult your doctor or pharmacist first.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

5. How to store Calmurid

- 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 and carton. The expiry date refers to the last day of that month.
 - Do not store above 25°C. Do not refrigerate or freeze.
- Do not throw away any medicines via wastewater or household waste. Ask your 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 Calmurid contains

- The active substances are urea and lactic acid. Each gram of Calmurid contains 100mg of urea and 50mg of lactic acid.
- The other ingredients are glyceryl monostearate, betaine monohydrate, diethanolamine cetyl phosphate, hard fat, cholesterol, sodium chloride and purified water.

What Calmurid looks like and contents of the pack

Calmurid is a white cream. It is available in 15 g, 20 g, 30 g, 50g and 100 g tubes and in 400 g and 500 g pump dispensers, either on prescription from your doctor or indirectly from your pharmacist.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Galderma (UK) Limited, Meridien House, 69-71 Clarendon Road, Watford, Herts., WD17 1DS, UK.

Manufacturer: Laboratoires Galderma, ZI-Montdésir, 74540 Alby-sur-Chéran, France.

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