

Lotriderm® 0.05% w/w /1.0% w/w Cream

Betamethasone (as dipropionate 0.064%)/clotrimazole

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

1. What Lotriderm cream is and what it is used for

Lotriderm Cream contains the active ingredients 0.064% w/w betamethasone dipropionate (equivalent to 0.05 % w/w betamethasone) and 1.0% w/w clotrimazole. Betamethasone belongs to a group of medicines called topical corticosteroids which are used on the surface of the skin to reduce the redness and itchiness caused by certain skin problems. Clotrimazole is a topical anti-fungal medicine used to treat some fungal infections of the skin.

Lotriderm Cream is used for the short-term treatment of certain fungal infections of the skin, when redness and itchiness may also be a problem.

2. What you need to know before you use Lotriderm Cream

Do not use Lotriderm Cream

- if you are allergic to betamethasone dipropionate, clotrimazole or any of the other ingredients of this medicine (listed in section 6).
- if your skin becomes irritated, or you develop an allergic reaction.
- on any other skin infections as it could make them worse, especially rosacea (a skin condition affecting the face), acne, dermatitis (skin inflammation) around the mouth, nappy rash or other skin infections.

Warnings and precautions

If you have psoriasis, your doctor may want to review your treatment regularly. Contact your doctor if your psoriasis gets worse or you get raised bumps filled with pus under your skin.

Contact your doctor immediately if you, or your child, experience blurred vision or other visual disturbances.

Side effects that may happen with inhaled or oral corticosteroids may also occur with corticosteroids used on the skin, especially in infants and children.

If you use more than the correct amount of cream and/or use it for longer than is recommended, it can affect the levels of certain hormones in the body, particularly in infants and children.

In adults the changes in hormone levels may lead rarely to puffiness or rounding of the face, weakness, tiredness, and dizziness when standing or sitting down.

Children

Do not use this medicine on children under 12 years of age unless advised by your doctor.

If you use more than the correct amount of cream and/or use it for longer than is recommended, it can affect your child's hormones. Rarely this may lead to:

- Delayed growth and development
- A moon face or rounding of the face
- A build-up of pressure around the brain which can produce
 - a bulging of the fontanelle (the soft spot in the top of the skull) in infants
 - a constant thumping headache
 - blurred vision or other visual disturbances

Other medicines and Lotriderm Cream

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

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.

Lotriderm Cream contains:

- cetostearyl alcohol, which may cause localised skin reactions (e.g. contact dermatitis).
- 100mg propylene glycol in each gram, which may cause skin irritation. Because this medicine contains propylene glycol, do not use it on open wounds or large areas of broken or damaged skin (such as burns) without checking with your doctor or pharmacist.
- 10mg benzyl alcohol in each gram, which may cause allergic reactions or mild local irritation.

3. How to use Lotriderm Cream

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

- For adults and children over the age of 12 years a layer of cream should be gently massaged into the affected and surrounding skin areas twice a day, in the morning and evening.
- Usually the cream should be used for either two weeks or four weeks, depending on the type of infection you have.
- Your doctor will tell you how long to use the cream for. Your skin infection should start to improve and the redness and itchiness will ease within the first few days of treatment.
- If your skin infection does not appear to get any better, you should see your doctor.

You should always follow these instructions when using Lotriderm Cream:

- Keep the cream away from your eyes.
- If Lotriderm Cream is used in children, it should not be used on any part of their body for more than 5 days.
- Do not put the cream under a dressing, such as a plaster or bandage, as this makes it easier for the active ingredient of the medicine to pass through the skin and possibly cause some unwanted effects.
- You must not use a large amount of cream on large areas of the body for a long time (for example every day for many weeks or months).
- Do not apply the cream to the face for more than 5 days, in places where the skin folds (e.g. the back of the knee) or on large areas of damaged skin.

If you use more Lotriderm Cream than you should

Tell your doctor if:

- you (or someone else) accidentally swallows the cream, it should not produce any undesirable effects.
- you use the cream more often than you should, or on large areas of the body, it may cause some side effects.
- you have not followed the dosage instructions, or your doctor's advice and have used the cream too frequently and/or for a long time

If you forget to use Lotriderm Cream

If you forget to use your cream at the right time, use it as soon as you remember, then carry on as before.

4. Possible side effects

A few people may find that they suffer from some of the following side effects after using Lotriderm Cream:

- burning and stinging
- rash; swelling and other skin infections.

In addition, the following side effects have been reported to occur following the use of other medicines containing either clotrimazole or betamethasone dipropionate:

- redness, stinging, blistering, peeling, swelling, itching, burning, skin rash, dryness of the skin
- inflammation of the hair follicles; excessive hair growth
- darkening of the skin; allergic skin reactions; dermatitis (skin inflammation) around the mouth; other skin infections, thinning of the skin and red marks.
- blurred vision.

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 at:

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 Lotriderm Cream

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater. 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 Lotriderm Cream contains

- The active substances are betamethasone dipropionate and clotrimazole. Each gram contains 0.64 mg betamethasone dipropionate (equivalent to 0.5 mg betamethasone) and 10 mg clotrimazole.
- The other ingredients are: liquid paraffin; white soft paraffin; cetostearyl alcohol; macrogol cetostearyl ether; benzyl alcohol; sodium dihydrogen phosphate dihydrate; phosphoric acid concentrated; sodium hydroxide; propylene glycol (E 1520); purified water.

What Lotriderm Cream looks like and contents of the pack

Lotriderm Cream is a smooth, white to off white cream. It is available in tubes containing 15g, 30g or 50g. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The holder of the Marketing Authorisation is: Organon Pharma (UK) Limited, Shotton Lane, Cramlington, United Kingdom, NE23 3JU.

The manufacturer is: Organon Heist bv, Industriepark 30, 2220 Heist-op-den-Berg, Belgium.

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