

MSD ARTWORK

Item No.: XXXXXX
 Revision Date & No.: XXXXXX-X
 Pharma Code: XXX
 Schawk Job No.: 492658A02

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Technical Info Profile

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Lotriderm® 0.064% w/w + 1% w/w
Cream
 Betamethasone dipropionate/clotrimazole

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

- What Lotriderm Cream is and what it is used for
- Before you use Lotriderm Cream
- How to use Lotriderm Cream
- Possible side effects
- How to store Lotriderm Cream
- Further information

1 WHAT LOTRIDERM CREAM IS AND WHAT IT IS USED FOR

Lotriderm Cream contains the active ingredients 0.064% w/w betamethasone dipropionate and 1.0% w/w clotrimazole which belong to a group of medicines called topical corticosteroids. These medicines 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 BEFORE YOU USE LOTRIDERM CREAM

Do not use Lotriderm Cream

- if you have ever had an allergic reaction to betamethasone dipropionate, clotrimazole, any other similar medicines or to any of the inactive ingredients in the cream.
- 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 around the mouth, nappy rash or other skin infections.
- for children under the age of 12 years.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant or breastfeeding, before you start using Lotriderm Cream.

Important information about some of the ingredients of Lotriderm Cream

Lotriderm Cream contains propylene glycol (E1520) which may cause skin irritation and cetostearyl alcohol which may cause local skin reactions such as dermatitis.

3 HOW TO USE LOTRIDERM CREAM

Always use Lotriderm Cream exactly as your doctor has told you. You should 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.
- Do not apply the cream to children, 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 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).

If you use more Lotriderm Cream than you should

If you (or someone else) accidentally swallows the cream, it should not produce any undesirable effects. However, if you are worried, you should see your doctor. If you use the cream more often than you should, or on large areas of the body, it may cause some side effects. If 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, you should tell your doctor.

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 around the mouth; other skin infections, thinning of the skin and red marks.

If you are worried by these or any other effects, you should tell your doctor or pharmacist.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 HOW TO STORE LOTRIDERM CREAM

- Keep out of the reach and sight of children.
- Do not store above 25°C.
- Do not use Lotriderm Cream after the expiry date which is stated on the label and carton after 'Exp'. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Lotriderm Cream contains

- Lotriderm Cream contains 0.064 % w/w betamethasone dipropionate and 1.0 % w/w 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; 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 30 g.

Marketing Authorisation Holder and Manufacturer

The holder of the Marketing Authorisation is:
 Merck Sharp & Dohme Ireland (Human Health) Limited, Red Oak North, South County Business Park, Leopardstown, Dublin 18, Ireland.

The manufacturer is:
 Schering-Plough Labo N.V., Industriepark 30 - Zone A, B-2220 Heist-op-den-Berg, Belgium.

This leaflet was last approved in November 2015

MSD

MSD PROFILE

Profile: IN33GR/V
 Profile Revision: 1
 Profile Revision Date: 230414
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 Folding Size 170 x 23 mm

Over Sticker Varnish Free Text Free

Pharma Code Braille Grid Tamper Evident

Profile Perforation Fold

Bar prints 100mm @ 100%

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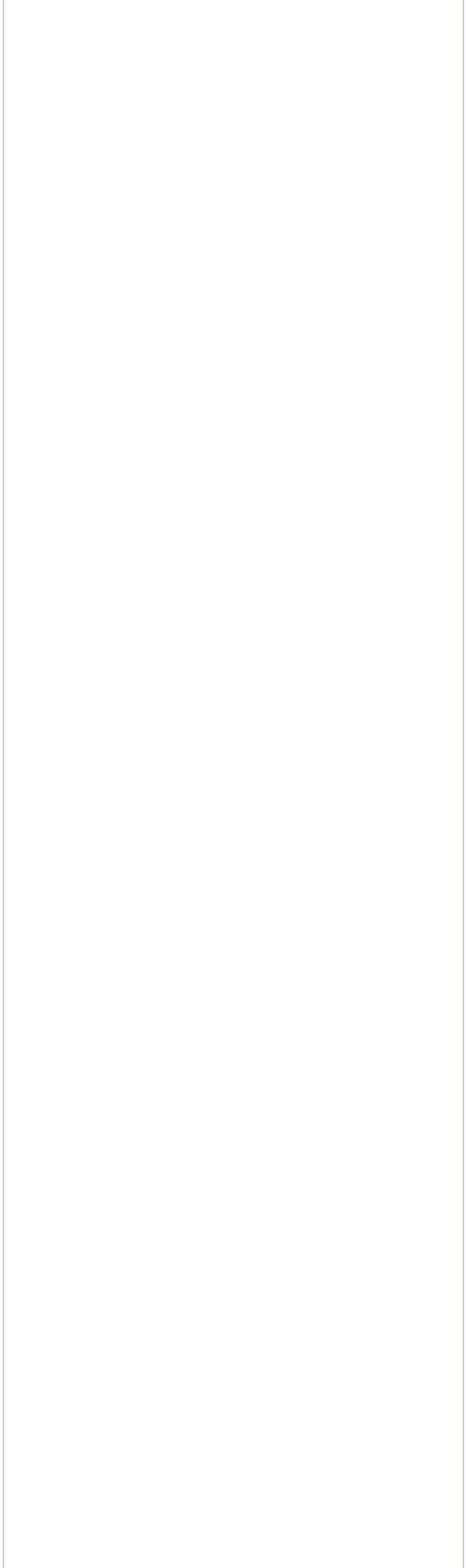
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