

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

☒ LOTRIDERM®
Clotrimazole and Betamethasone Dipropionate Cream

Read this carefully before you start taking LOTRIDERM® and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about LOTRIDERM®.

What is LOTRIDERM® used for?

LOTRIDERM® is used to treat the following skin infections caused by a fungus:

- athlete's foot (tinea pedis)
- jock itch (tinea cruris)
- ringworm (tinea corporis)

How does LOTRIDERM® work?

LOTRIDERM® contains two medicines, betamethasone dipropionate and clotrimazole. Clotrimazole interferes with the growth of the fungus that is causing your skin problem. Betamethasone dipropionate reduces the swelling, redness and itching of your skin.

What are the ingredients in LOTRIDERM®?

Medicinal ingredients: betamethasone dipropionate and clotrimazole

Non-medicinal ingredients: cetostearyl alcohol, liquid paraffin, macrogol cetostearyl ether, phosphoric acid, propylene glycol, sodium dihydrogen phosphate dihydrate, sodium hydroxide, white soft paraffin; benzyl alcohol as preservative.

LOTRIDERM® comes in the following dosage forms:

As a cream containing 0.05 % betamethasone dipropionate and 1.0 % clotrimazole.

Do not use LOTRIDERM® if you:

- are allergic to betamethasone dipropionate or clotrimazole
- are allergic to any of the other ingredients in LOTRIDERM® or to a component of the container
- are allergic to a medicine similar to that in LOTRIDERM® called a corticosteroid or an imidazole
- have any untreated skin infection
- have certain viral diseases such as herpes simplex, chicken pox or vaccinia

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LOTRIDERM®. Talk about any health conditions or problems you may have, including if you:

- are pregnant or planning on becoming pregnant. It is not known if LOTRIDERM® can harm your unborn baby. Your health care professional will decide whether giving you LOTRIDERM® outweighs the potential risk to the unborn baby.

- are breastfeeding or planning to breastfeed. It is not known whether LOTRIDERM[®] can pass into your breastmilk. Your healthcare professional will decide whether you should stop breastfeeding or stop the use of LOTRIDERM[®].
- have diseases of your skin that are caused by poor blood flow. An example is a disease called stasis dermatitis.

Other warnings you should know about:

Use in children:

It is not known if LOTRIDERM[®] is safe and effective in children less than 12 years of age. Use of LOTRIDERM[®] in children should be limited. Long-term use of this medicine may affect your child's hormones. This may affect your child's growth and development. LOTRIDERM[®] cream should not be used to treat diaper rash or redness. You should avoid applying LOTRIDERM[®] cream in the diaper area of a child.

Eyes:

Do not use LOTRIDERM[®] in or near your eyes. Talk to your healthcare professional if you develop blurred vision or other eye problems while using LOTRIDERM[®].

Skin:

Do not use too much LOTRIDERM[®] on large areas of your body. Talk to your healthcare professional if you develop sensitive skin or irritation, extremely dry skin, scaling or flaking of your skin or stretch marks (striae). These symptoms may happen if you use LOTRIDERM[®] for a long time. Your healthcare professional may need to stop your treatment.

Use of too much LOTRIDERM[®] on large areas of the skin or for too long may lead to serious problems. These include changes in your hormone levels, Cushing's disease, a condition where your body produces too much cortisol and changes in your sugar levels. You should not use too much LOTRIDERM[®] on large areas of your skin. Talk to your healthcare professional if you are not sure how to safely apply LOTRIDERM[®].

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take LOTRIDERM[®]:

- Follow all instructions given to you by your healthcare professional.
- Apply a thin layer to the affected and surrounding skin area.
- Make sure the cream covers the entire affected area.
- Do not cover the treated areas with a bandage, plaster or wrap of any kind. This can lead to serious side effects.
- The use of LOTRIDERM[®] for longer than four weeks is not recommended.

Usual dose:

LOTRIDERM[®] should be applied twice a day, in the morning and at night. It is usually applied for two weeks for jock itch (tinea cruris) and ring worm (tinea corporis). It is usually applied for four weeks for athlete's foot (tinea pedis). Your healthcare professional will tell you exactly

for how long you should use LOTRIDERM[®]. It is not recommended that LOTRIDERM[®] be used for longer than four weeks.

Overdose:

If you think you have applied too much LOTRIDERM[®], contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed dose

If you miss a dose, apply it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not apply a double dose to make up for a missed dose.

What are possible side effects from using LOTRIDERM[®]?

These are not all the possible side effects you may feel when using LOTRIDERM[®]. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include the following:

- Burning, itching, irritation, dryness, blistering, stinging, redness or swelling of the skin
- New skin infection
- Thinning of the skin
- Swelling of the hair follicles
- Excessive hair growth
- Acne outbreaks that result in redness and blushing
- Patches of lighter skin tone
- Skin redness around the mouth
- Rash
- Stretch marks (striae)
- Peeling of the skin
- Hives
- General skin irritation
- A feeling of tingling or of pins and needles on your skin (paresthesia)
- Blurred vision

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 15°C and 30°C.

Keep out of reach and sight of children.

If you want more information about LOTRIDERM®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website www.organon.ca, or by calling 1-844-820-5468.

This leaflet was prepared by Organon Canada Inc.

Last Revised: April 20, 2021

® N.V. Organon. Used under license.

© 2021 Organon Canada Inc. All rights reserved.