Product name: **Lotriderm cream**	**1.5.5.4 PROPOSED PATIENT INFORMATION LEAFLET CLEAN COPY** Date of Revision: 25 October 2023
Applicant: Organon South Africa (Pty) Ltd	

SCHEDULING STATUS

S4

LOTRIDERM® Cream

Betamethasone (as diproprionate) 0,5 mg and clotrimazole 10 mg

Read all of this leaflet carefully before you start using LOTRIDERM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- LOTRIDERM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

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1. What LOTRIDERM is and what it is used for

LOTRIDERM Cream contains a cortisone-type medicine with an antifungal activity.

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

Do not use DLOTRIDERM Cream:

- If you are allergic (hypersensitive) to betamethasone diproprionate and clotrimazole or any of the other ingredients of LOTRIDERM Cream.
- If you are under the treatment of herpes infections, vaccine reactions or chicken pox (varicella).

Warnings and precautions

Take special care with LOTRIDERM Cream

- LOTRIDERM Cream is for use only on the skin. Avoid contact with the eyes. Use with particular caution on facial skin and only for short periods.
- Do not use LOTRIDERM Cream on large areas of the body, as this will increase the amount absorbed.
- Do not use LOTRIDERM Cream more often or for a longer time than your doctor recommends.
- Check with your doctor if your skin condition worsens or seems to be infected.

- Do not use LOTRIDERM Cream in any skin crease areas.
- Do not use LOTRIDERM Cream in nappy areas in infants.
- Children and adolescents who must use LOTRIDERM Cream should be followed closely by their doctor, since LOTRIDERM Cream is absorbed through the skin and can affect growth or cause other unwanted effects. LOTRIDERM Cream should ideally not be used in infants and young children at all.
- Contact your doctor if you experience visual disturbances including blurred vision.

If there is a worsening of your condition during use consult your doctor – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment.

If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the cream without consulting your doctor unless your doctor has previously advised you to do so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

Other medicines and LOTRIDERM Cream

Always tell your healthcare provider if you are taking any other medicine (this includes all complementary or traditional medicines).

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using this medicine.

The use of LOTRIDERM Cream is not recommended for mothers who are breastfeeding.

Driving and using machinery

It is not always possible to predict to what extent LOTRIDERM may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which LOTRIDERM affects them.

LOTRIDERM cream has no influence on the ability to drive and use machines.

3. How to use LOTRIDERM

Do not share medicines prescribed for you with any other person.

Always use LOTRIDERM Cream exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Apply a thin film of LOTRIDERM Cream to cover the affected area and massage in gently, usually twice a day (morning and night) or as directed by your doctor.

Do not bandage or otherwise wrap the skin being treated unless directed to do so by your doctor. Do not use tight-fitting diapers or plastic pants on a child being treated with LOTRIDERM Cream unless directed to do so by your doctor. Do not apply LOTRIDERM Cream to deep skin wounds, puncture wounds, serious burns or raw areas.

If you have the impression that the effect of LOTRIDERM Cream is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will tell you how long your treatment with LOTRIDERM Cream will last. Do not stop treatment early.

If you use more LOTRIDERM Cream than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

If you forget to use LOTRIDERM Cream

Do not use a double dose to make up for forgotten individual applications. If you miss one application, apply your next dose as usual.

If you stop using LOTRIDERM Cream

If you stop using LOTRIDERM Cream, you will lose the effects of LOTRIDERM Cream. You should not stop using LOTRIDERM Cream, unless your doctor tells you as your symptoms may return.

4. Possible side effects

LOTRIDERM Cream can have side effects.

The following have been reported and the frequencies are unknown:

- Redness, stinging, blistering, peeling, swelling, itching, burning, skin rash, dryness of the skin.
- Inflammation of the hair follicles, excessive hair growth.
- Pale areas of the skin, allergic skin reactions, dermatitis around the mouth, other skin infections, thinning of the skin and red marks.
- Blurred vision.

Steroid withdrawal reaction:

If used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

Not all side effects reported for LOTRIDERM Cream are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using LOTRIDERM Cream, please consult your healthcare provider for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get 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 to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of LOTRIDERM Cream.

5. How to store LOTRIDERM

Store at or below 25°C.

Store all medicines out of the reach of children.

Do not use after the expiry date stated on the tube and on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LOTRIDERM contains

Each gram of cream contains 0,5 mg betamethasone (as dipropionate) and 10 mg clotrimazole.

Preservative: Benzyl alcohol 1 % *m/m*

The other ingredients are: Cetomacrogol 1 000, cetostearyl alcohol, liquid paraffin, phosphoric acid, propylene glycol, sodium acid phosphate, sodium hydroxide, white soft paraffin and purified water.

What LOTRIDERM looks like and contents of the pack

LOTRIDERM Cream is a smooth, white to off-white cream.

LOTRIDERM Cream is packed in tubes of 20 g in cartons.

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Holder of Certificate of Registration

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