PROPOSED PATIENT INFORMATION LEAFLET FOR

MAXADERM

SCHEDULING STATUS: S4

MAXADERM 10 mg / 1 mg, cream

Isoconazole nitrate / Diflucortolone valerate

Contains preservatives:

Propyl hydroxybenzoate 0,04 % m/m

Methyl hydroxybenzoate 0,16 % m/m

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

- Keep this leaflet; you may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- MAXADERM 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 MAXADERM is and what it is used for
2. What you need to know before you use MAXADERM
3. How to use MAXADERM
4. Possible side effects
5. How to store MAXADERM
6. Contents of the pack and other information.

1. What MAXADERM is and what it is used for

MAXADERM cream is used to treat fungal infections of the skin, groin and genital regions where inflammation or eczema of the skin is also a problem.

2. What you need to know before you use MAXADERM

Do not use MAXADERM:

- if you are hypersensitive (allergic) to isoconazole nitrate / diflucortolone valerate or any of the other ingredients of MAXADERM (listed in section **6**).
- if you have a viral infection such as herpes simplex, vaccinia or varicella.
- if you have tuberculosis of the skin.
- if you are pregnant. Corticosteroids can be teratogenic in animals when applied to the skin.
- on any skin crease areas.
- under a waterproof dressing when applying to large areas of the body.
- if you are suffering from rosacea.
- if you are using MAXADERM for pruritus.
- safe use of MAXADERM when you are breast feeding has not been proven.

Warnings and precautions

Take special care with MAXADERM:

- You should discontinue treatment if unfavourable reaction occurs.
- Antimicrobial treatment should be started if you have a secondary skin infection.
- You should take particular caution when using MAXADERM for facial dermatosis and should only use the product for a short period.
- You should not allow MAXADERM to come into contact with your eyes.

- Applying MAXADERM to the eyelids has caused raised intraocular pressure, corneal ulcers and reduced visual function.
- Glaucoma may develop from using topical corticosteroids such as MAXADERM (for example, after large-dosed or extensive application over a prolonged period, occlusive dressing techniques, or application to the skin around the eyes).
- Treating psoriasis with MAXADERM may provoke the pustular form of psoriasis.
- You should not apply MAXADERM to ulcers of the leg.
- You should avoid using MAXADERM for long periods of time, especially if the patient is a child.
- In infections of the spaces between toes or fingers, it is advisable to place a strip of gauze smeared with MAXADERM between the toes or fingers.
- To avoid renewed infection, you should change your personal linen daily (washcloth, towel, underwear - preferably all of cotton) and these should be washed in very hot or even boiling water.
- Regular personal hygiene is essential for successful MAXADERM treatment. In athlete's foot (tinea pedis), the space between your toes must be thoroughly dried after washing, and stockings or socks should be changed daily.

- If there is a worsening of your condition during use consult your prescriber – 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/ointment without consulting your prescriber unless your prescriber 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.

Children

No data available.

Other medicines and MAXADERM

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking MAXADERM.

You should not use MAXADERM if you are pregnant, as there is limited information available on the safe use during pregnancy.

You should not use MAXADERM if you are breastfeeding your child, as there is limited information available on the safe use during breastfeeding.

You should also not be treated with MAXADERM on your breast, as your child may swallow some cream, which may be harmful.

MAXADERM should not interfere with your fertility or ability to have a child.

Driving and using machines

It is safe to use MAXADERM when diving or using machinery.

It is not always possible to predict to what extent MAXADERM 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 MAXADERM affects them.

3. How to use MAXADERM

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

Always use MAXADERM exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

You should apply MAXADERM twice a day to the affected areas of skin.

In co-ordination with your doctor, you should stop treatment with MAXADERM after the inflammatory or eczematous skin condition has gone away. Your doctor may prescribe follow-up treatment with a corticosteroid-free preparation. This applies in particular to use in the groin and genital regions.

If you have the impression that the effect of MAXADERM is too strong or too weak, tell your doctor or pharmacist.

If you use more MAXADERM than you should

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

If you forget to use MAXADERM

Do not use increased amounts to make up for forgotten doses.

If you stop using MAXADERM

Consult with your doctor before stopping or interrupting treatment with MAXADERM.

4. Possible side effects

MAXADERM can have side effects.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Irritation at application site
- Burning at application site

Less frequent side effects:

- Striae (Stretch marks)
- Erythema (skin redness) at application site
- Dryness at application site

Side effects with unknown frequency:

- Blurred vision
- Itching at application site
- Blisters at application site

- Steroidal 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.

You should avoid using MAXADERM continuously for prolonged periods of time (more than 4 weeks) as symptoms such as thinning of the skin, loss of elasticity, dilatation of superficial blood vessels, telangiectasiae and ecchymoses can occur. Increased fragility of cutaneous vessels may result in bruising and purpura. This is most likely to occur on the face and when waterproof dressings are used.

Systemic absorption of MAXADERM applied to the skin may occur, especially under the following conditions when large quantities are used, when applied to large areas of the body, to damaged skin or when waterproof dressings are used: Depression of the hypothalamic-pituitary-adrenal axis with subsequent suppression of the adrenal gland may occur and may be precipitated by an infection or trauma. These effects are most likely to be severe in children. Growth retardation and a Cushingoid state may be produced. Benign intracranial hypertension has been reported.

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, pharmacist or nurse. 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 or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of MAXADERM.

5. How to store MAXADERM

Store at or below 25 °C.

Keep out of reach of children.

For external use only.

Do not use after the expiry date stated on the container.

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 MAXADERM contains

The active substances are isoconazole nitrate and diflucortolone valerate.

The other ingredients are polyoxyl 35 castor oil, liquid paraffin, cetostearyl alcohol, cetomacrogol 1200, macrogol cetostearyl ether, propyl hydroxybenzoate, methyl hydroxybenzoate, citric acid monohydrate, sodium citrate dehydrate, propylene glycol and purified water.

What MAXADERM looks like and contents of the pack

Ice white coloured homogenous cream with no visible particles or separation.

20 g aluminium collapsible tube coated with white polyester coating and with a white polypropylene cap.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

Rosen Heights,

Pasita Street,

Rosen Park,

Bellville,

7530.

Customer Care: 080 222 6662

This leaflet was last revised in

First authorisation: 30 October 2000

Revision: 02 February 2024

Registration number(s)

33/13.4.1/0303

Namibia: NS2 11/13.4.1/0177

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.