PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Mentax Cream

The cream contains Butenafine Hydrochloride at a concentration of 1%.
Inactive ingredients: see section 6 in this leaflet.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. Keep this leaflet. You may want to read it again. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for you only, to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.
This medicine is not intended for infants and children below the age of 12.

1. WHAT IS THE MEDICINE INTENDED FOR?

An antifungal preparation for interdigital tinea pedis (athlete's foot), tinea corporis (ringworm) and tinea cruris (jock itch).
Use of this preparation for ringworm and jock itch is for a period of up to 4 weeks.
Therapeutic group: Antifungal.

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine if:
You are sensitive (allergic) to butenafine hydrochloride or to any of the other ingredients in Mentax Cream (see section 6 in this leaflet).
Special attention and caution are required if you are sensitive to allylamine antifungals, as you may also be sensitive to Mentax Cream.

❗ Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

❗ If you are pregnant or breastfeeding, consult the doctor before using Mentax Cream.
In any case, breastfeeding women must abstain from applying the preparation to the breast area.

3. HOW SHOULD YOU USE THE MEDICINE?

- Always use according to the doctor's instructions.
- Check with the doctor or pharmacist if you are uncertain.
- The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally:
For treatment of athlete's foot, use Mentax Cream twice a day for 7 days, or once a day for 4 weeks.
For treatment of ringworm and jock itch, use Mentax Cream once a day for two weeks.
Do not exceed the recommended dose.
Avoid contact of the preparation with the eyes and mucosal tissues (e.g., mouth and nose). In case of contact with the eyes, wash them thoroughly with water.
Do not swallow! This preparation is intended for external use only.
The recommended way of using Mentax Cream is as follows:
1) The treatment site must be dry before using Mentax Cream. If you want to use the preparation after a shower, dry the treatment site very well.
2) Apply a sufficient amount of Mentax Cream to cover the entire treatment site.
3) Do not exceed the recommended dose.
4) Do not dress the treated area, unless you have been instructed otherwise by the doctor.
5) Wash your hands thoroughly after using Mentax Cream.

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- Do not use Mentax Cream to treat any other health problem aside from that for which it was prescribed.
- Adhere to the treatment regimen recommended by the doctor. Even if there is an improvement in your health, do not discontinue treatment without consulting the doctor.
- Inform the doctor if there is no improvement at the end of the treatment period he/she has set, or if your medical condition worsened during the course of treatment.
- Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
- If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

- As with any medicine, use of Mentax Cream may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Discontinue treatment and refer to the doctor immediately:
If irritation, itching, tenderness, burning, blisters, swelling, local rash or inflammation, that did not exist prior to use of the preparation, occur (rare).
- In addition to the desired effect of the preparation, mild irritation or skin redness may occur at the application site.
- If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, or if there is a change in your general health, consult with the doctor immediately.

Reporting side effects:
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il
In addition, you can report to Perrigo via the following address:
www.perrigo-pharma.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This preparation and any other medicine must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Store in a cool place in the original package, below 25°C.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Can be used for 3 months after first opening, but not later than the expiry date.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains the following inactive ingredients:
  Purified water, propylene glycol dicaprilate, cetyl alcohol, glyceryl monostearate, glycerine, white soft paraffin, stearic acid, diethanolamine, polyoxylethylene cetyl ether, sodium benzoate.
- What does the medicine look like and what are the contents of the package:
  An aluminum tube, with a white plastic cap, containing 10 grams of cream, for multiple use.
- Manufacturer, registration holder and address: Perrigo Israel Pharmaceuticals Ltd., P.O.B. 16, Yeruham.
- This leaflet was checked and approved by the Ministry of Health in July 2013.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 11063.28947