

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

The medicine is dispensed with a doctor's prescription only

Topisalen ointment

Active ingredients:

Flumethasone pivalate 0.02%

Salicylic acid 3%

For inactive ingredients in the preparation - see section 6 "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar. The medicine is not intended for infants under 2 years of age.

Do not use on large skin areas, open or infected wounds, inflamed skin, moles or birthmarks. Avoid occlusive dressings on the affected area (baby diapers are an occlusive dressing).

Special care is required when using in children and adolescents. Use in these age groups requires medical supervision.

If your condition does not improve within one week or if your condition worsens, refer to the doctor.

1. WHAT IS THE MEDICINE INTENDED FOR?

For local treatment in cases of corticosteroid-responsive dermatoses, especially in cases of hyperkeratosis.

Therapeutic group: Flumethasone pivalate is a corticosteroid.
Salicylic acid is a keratolytic agent.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You have a known sensitivity to any of the medicine's ingredients, to aspirin, salicylates and other nonsteroidal anti-inflammatory drugs (NSAIDs).
- You are suffering from a viral infection (e.g., herpes or chickenpox), fungal infections or skin tuberculosis.
- Do not use in infants under 2 years of age.

Special warnings regarding use of the medicine

- If you are sensitive to any type of food or medicine, inform the doctor before using the medicine.
- Do not use the preparation for any purpose other than that for which it was prescribed.
- Do not use this medicine on large skin areas, open or infected wounds, inflamed skin, moles or birthmarks.
- When necessary, use the minimum required amount on the skin of the face, groin and armpit.
- Do not allow the medicine to come into contact with the eyes. In case of such contact, immediately rinse thoroughly with water for 15 minutes.
- Special care is required when using in children and adolescents. Use in these age groups requires medical supervision due to increased risk of absorption of the preparation into the bloodstream.
- When using the preparation for a prolonged period: inform the doctor if you suffer from glaucoma, cataract or kidney disease.
- Avoid occlusive dressings on the affected area (baby diapers are an occlusive dressing).
- If there is no improvement in your condition within one week or if your condition worsens, refer to the doctor.

Before treatment with Topisalen, tell the doctor if:

- you are pregnant or breastfeeding;
- you are suffering, or have suffered in the past, from impaired function of the peripheral blood vessels, the liver, the kidney/urinary system, the immune system, from diabetes (in prolonged use).

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is especially important to inform the doctor or pharmacist if you are taking: Medicines for local treatment of acne, medicines that contain alcohol or any other preparation that may cause dryness and/or peeling of the skin.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, consult the doctor before using the medicine.

Infants and children:

The medicine is not intended for infants under 2 years of age.

Do not treat infants and children for more than two weeks without explicit instructions from the doctor. Unless instructed by the doctor, avoid occlusive dressings on the affected area (baby diapers are an occlusive dressing).

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. If you are uncertain about the directions for use, ask the doctor or pharmacist.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally: 2-4 times a day.

Do not exceed the recommended dose.

Apply, with clean hands, an amount of ointment sufficient to cover the affected area. Rub in lightly to allow penetration of the ointment into the skin. Wash your hands thoroughly after use (unless the hands are the treated area).

Do not swallow! For external use only. Avoid contact of the preparation with the eyes or mucosal tissue (such as: in the nose and/or mouth).

If there is no improvement in your condition within one week or if your condition worsens, refer to the doctor.

If you accidentally took an overdose or if a child has accidentally swallowed the medicine, refer to the doctor or proceed to a hospital emergency room immediately and bring the package of the medicine with you.

If you forget to take the medicine at the required time, do not take a double dose. Take the next dose at the regular time and consult the doctor.

Adhere to the treatment as recommended by the doctor.

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 Topisalen 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.

Stop treatment and refer to the doctor immediately if the following effects occur:

- Irritation, rash, local infection or inflammation (that were not evident before treatment with the preparation).
- Symptoms that can be indicative of salicylic acid poisoning (due to prolonged use on large areas), such as: nausea/vomiting, diarrhea, dizziness, tiredness, tinnitus, loss of hearing, etc.

Additional side effects:

Refer to the doctor if the following effects persist: redness, feeling of local warmth/pain, stinging, itchiness, peeling of the skin, dry skin.

If one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine 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.
- Do not use the medicine after the expiry date (exp. date) that appears on the package/tube. The expiry date refers to the last day of that month.
- Store in a cool place, below 25°C.

6. FURTHER INFORMATION

- In addition to the active ingredients, the medicine also contains: Polyethylene, liquid paraffin, propylene glycol, sorbitan mono-oleate, propyl hydroxybenzoate.
- **What does the medicine look like and what are the contents of the package?**
A tube containing 15 g white-colored ointment.
- **Manufacturer and license holder:** TRIMA, Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.
- This leaflet was checked and approved by the Ministry of Health on 18.02.2013.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 023.58.21362.00.

Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

TRIMA