PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Threolone®

Skin ointment

Composition

Chloramphenicol	3.0%
Prednisolone	0.5%

For information regarding inactive ingredients and allergens, see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Additional information".

Read the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

An antibiotic and anti-inflammatory ointment for use on the skin.

Therapeutic class

Chloramphenicol: Antibiotic

Prednisolone: Anti-inflammatory corticosteroid

2. Before using the medicine

Do not use this medicine:

- If you are sensitive (allergic) to chloramphenicol, prednisolone or any of the other ingredients the medicine contains (for a list of inactive ingredients, see section 6 – "Additional information").
- In cases of viral infections (such as herpes or chickenpox), fungal infections or tuberculosis of the skin.
- In the case of a perforated eardrum.
- If there is a family history of, or you suffer from blood system disorders, including aplastic anemia.
- Not to be used in the eyes.

Special warnings regarding the use of the medicine

- There are rare reports of effects such as partial development of bone marrow and aplastic anemia after local use of preparations that contained chloramphenicol.
- In cases of severe infections, in parallel to using the medicine, appropriate systemic treatment should be administered.
- Avoid prolonged use of the preparation, as it may increase the risk of developing resistance to the preparation. If new infections appear during the course of treatment, stop the treatment and refer to the doctor.
- Do not use the preparation for any purpose other than that for which it was prescribed.
- Do not use this medicine frequently, over extensive areas of skin or on open wounds.
- The preparation is not intended to be used in the eyes, do not allow the preparation to come into contact with them. In case of contact with the eyes, wash them immediately with water.
- If the preparation is used over extensive areas of skin with occlusive measures such as dressings or diapers, there is a risk of increased absorption of the preparation into the blood. Caution must therefore be exercised in patients suffering from electrolyte imbalance, digestive disturbances, diabetes, muscle disease (myopathy), cataract, impaired function of the liver or kidney, osteoporosis or bleeding.

Before treatment with Threolone, inform the doctor if:

- You are pregnant.
- You are breastfeeding.
- You suffer or have suffered in the past, from impaired function of the bone marrow or the immune system.
- You are sensitive to any type of food or medicine.

Children and adolescents

Special caution is required when used on children and adolescents. Use in these age groups must be accompanied by medical supervision.

The elderly

It is recommended to adjust the dosage in elderly patients to their medical condition.

Tests and follow-up

This preparation contains chloramphenicol, which may cause changes in the blood profile during prolonged or periodic use. It is therefore recommended to perform blood tests before starting the treatment and at regular intervals during the course of treatment, in order to identify blood profile abnormalities.

Drug interactions

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

Especially if you are taking medicines that suppress bone marrow function.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, consult with the doctor before starting the treatment.

Important information about some of the ingredients of the medicine

The preparation contains the ingredient Lanolin anhydrous, which may cause skin irritation (e.g., contact dermatitis).

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

- The dosage and treatment regimen will be determined only by the doctor.

The generally accepted dosage is:

Unless otherwise prescribed by your doctor, apply a thin layer to the affected area 2-4 times daily.

- Do not apply near the eyes.
- If there is no improvement in your condition within a few days or if your condition worsens, contact the doctor again.
- Do not use this preparation in infants and children under 4 years of age for more than two weeks, except under an explicit order from the doctor, especially on areas covered by diapers.
- Unless recommended by the doctor, occlusive dressing of the affected area should be avoided (plastic diapers are considered an occlusive dressing).

Do not exceed the recommended dose.

How to use

- Do not swallow, for external use only.
- Avoid contact with the eyes, mucous membranes (e.g., in the mouth, nose and ear) (see section 2 "Before using the medicine").

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

If you have forgotten to use this medicine at the required time, do not use a double dose. Use the next dose at the regular time and consult with a doctor.

Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting a doctor.

Do not take medicines in the dark! Check the label and the dose <u>every time</u> you take the medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Threolone may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Discontinue use and contact a doctor immediately if the following side effects occur:

- Bone marrow suppression
- Aplastic anemia
- Subcutaneous edema (angioneurotic edema)
- Anaphylactic shock
- Hives
- Fever
- Skin inflammation
- Wheezing
- Swelling of the face, lips or tongue
- Reduced blood count which manifests in fever, sore throat, tiredness, bleeding or weakness,
- local irritation, rash or inflammation (that were not present before using the preparation) (rare)
- Systemic absorption of the preparation which may cause:
  - Reversible suppression of the HPA pathway (Hypothalamic pituitary adrenal – a hormonal pathway that regulates the secretion of cortisol). Symptoms include tiredness, depression, anxiety, immunosuppression.
  - Cushing's syndrome. Symptoms include weight gain, reddening of the face and neck, increased body and facial hair growth, rise in blood pressure, bone atrophy, skin and muscle atrophy, increased blood glucose level and sometimes cognitive disturbances.
  - High blood sugar level.
  - Excretion of sugar in the urine.

These effects may occur at a higher frequency when occlusive dressings or diapers are used.

Contact the doctor immediately if:

The following side effects appear for the first time after the treatment is complete: fever or sore throat.

Other side effects that may occur:

- Redness
- A localized feeling of warmth (burning)
- Tingling
- Itch, irritation
- Dryness
- Inflammation of skin hair follicles
- Increased hairiness (hypertrichosis)
- Appearance of acne/pimples (also possible around the mouth)
- Hypopigmentation (lightening of the skin or appearance of spots in the treated area, which are lighter than the shade of the skin)
- Contact dermatitis
- Skin softening
- Skin atrophy
- Stretch marks (skin striae)
- Rash which is sometimes accompanied by a feeling of local heat (miliaria)

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

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link:

https://sideeffects.health.gov.il

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Store this preparation in a dark place below 25°C.

Do not discard medicines in wastewater or domestic trash. Ask your pharmacist how to discard medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, the medicine also contains:

Petrolatum yellow (paraffin, yellow soft), lanolin anhydrous (wool fat), mineral oil (paraffin liquid), colloidal silicon dioxide.

What does the medicine look like and what are the contents of the package:

A yellowish ointment.

The pack contains a tube of 10 grams.

Name and address of the manufacturer and marketing authorization holder:

Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.

The leaflet was revised in January 2022 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 027.40.21618

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