

**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 the medicine if:

- You are sensitive (allergic) to chloramphenicol, prednisolone or to any of the other ingredients this medicine contains (see below in the section "Important information about some of the ingredients of the medicine" and section 6 "Additional information").
- You have had problems in the blood (especially a decrease in the number of blood cells) during previous treatment with chloramphenicol.
- You have a family history of blood problems such as low amount of white blood cells, red blood cells or platelets.
- You or a member of your family has had blood or bone marrow problems. These problems may include a severe drop in the amount of red blood cells or a lower than normal blood count.
- You suffer from viral infections such as cold sores, herpes or chickenpox.
- You suffer from fungal infections, e.g. athlete's foot, tinea capitis or oral thrush.
- You suffer from blisters in the skin or sores caused by a bacterial infection such as impetigo, tuberculosis of the skin.
- You have a perforated eardrum.
- Not to be used in the eyes.

##### Special warnings regarding the use of the medicine

- In cases of severe infections, in parallel to using the medicine, appropriate systemic treatment should be administered.
- Avoid prolonged use of the medicine, as it may increase the risk of developing resistance to the medicine. If new infections appear during the course of treatment, stop the treatment and refer to the doctor.
- Do not use this medicine frequently and do not use it over extensive areas of skin or on open wounds.
- The medicine contains chloramphenicol, which may cause changes in the blood profile upon prolonged use. Therefore, prolonged use of the medicine should be avoided.
- The medicine is not intended to be used in the eyes; avoid contact with them. In case of contact with the eyes, wash them immediately with water.
- Consult a doctor before using the ointment with occlusive measures such as dressings or diapers, since there is a risk of absorption of the medicine into the blood.
- If your condition worsens during treatment, you may be having an allergic reaction or infection or a different treatment is required.
- If you experience a recurrence of your pre-treatment condition shortly after the end of treatment, within two weeks, the treatment should not be repeated without consulting the doctor, unless the doctor has instructed you beforehand to repeat the treatment in such a case. If your condition has improved but you experience a recurrence of your pre-treatment condition, and the redness extends beyond the area that was affected before starting treatment and you experience a

burning sensation, refer to the doctor.

- The ointment contains paraffin. Fabrics (clothes, bedding, dressings, etc.) that have been in contact with the medicine may ignite and burn more easily. Do not smoke or expose yourself to open fire due to the risk of severe burns. Washing the fabrics may reduce the risk but cannot totally remove it.

#### Children and adolescents

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

#### Tests and follow-up

This medicine contains chloramphenicol, which may cause changes in the blood profile upon prolonged or intermittent 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 affect bone marrow function (medicines that decrease the activity of the bone marrow and cause low blood count), such as azathioprine, or if you are receiving chemotherapy.**

#### Pregnancy and breastfeeding

Do not use Threolone during pregnancy or during breastfeeding, unless the doctor decides it is essential, as the effects of the medicine are unknown.

If you are pregnant or breastfeeding, think you are pregnant or are planning a pregnancy, consult the doctor or pharmacist before using the medicine.

#### Important information about some of the ingredients of the medicine

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

#### 3. HOW SHOULD YOU USE THE MEDICINE?

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

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

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

The generally accepted dosage is:

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

- Do not apply in the area of 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 medicine in infants and children under 4 years of age for more than two weeks, unless explicitly instructed to do so by 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

##### Method of use

- Do not swallow. For external use only.
- Avoid contact with the eyes, mucous membranes (e.g. in the mouth, nose and ears).

**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 every time you take a 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.

**If the following side effects occur, stop using the medicine and refer to the doctor immediately:**

- Allergic reactions, including:

shortness of breath, fever, swelling of the face, lips or tongue, itch or rash with swelling of the skin (the rash can be swollen or blotchy, or look like small blisters), mouth sores or sore throat that cause swallowing or breathing difficulties, swelling of the arms, legs or ankles.

- Sore throat, bruising or inability to overcome infections. In very rare cases, patients treated with chloramphenicol have experienced changes in the blood cells that resulted in great tiredness or easy bruising.

A new infection develops during treatment with the ointment. If this happens, inform the doctor. The use of chloramphenicol on the skin can sometimes lead to the development of resistant microorganisms such as fungi.

The condition of the skin worsens or the skin becomes swollen during treatment. You may be allergic to the medicine, have an infection or need a different treatment.

#### Possible side effects include:

- Burning
- Mild tingling
- Mild inflammation of the skin (dermatitis)
- Irritation or itching where the ointment is applied
- Increased hair growth and skin discoloration

**Side effects in cases of prolonged use, when a large amount of the ointment is used each time or when used under an occlusive dressing or diaper**

- Thinning of the skin, which may be damaged more easily
- Weight gain, rounding of the face and high blood pressure. These effects may occur more in babies and children.

#### Rare side effects include:

- Bone marrow suppression (a condition in which the bone marrow is unable to produce blood cells)
- Reduced production and death of red blood cells (anemia)

**Symptoms of steroid withdrawal:** after continuous use for long periods, withdrawal symptoms may appear upon discontinuation of use, including: redness of the skin which may extend beyond the initial treatment area, burning or tingling sensation, intense itching, peeling of the skin, oozing sores.

**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 the 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](http://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.

**This medicine should be kept 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 license holder** Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020

**This leaflet was revised in August 2024.**

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