Summary of Product Characteristics

Threolone
Topical Ointment

1. NAME OF THE MEDICINAL PRODUCT
Threolone

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition

Active Ingredients

Chloramphenicol	3.0% w/w
Prednisolone	0.5% w/w

Excipient with known effect
Lanolin anhydrous (wool fat).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Topical ointment
Yellowish homogenous ointment

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Infected eczema, pruritic lesions, angular stomatitis, impetigo, external otitis and pyoderma, and other skin infections caused by organisms sensitive to chloramphenicol.

4.2 Posology and method of administration
A thin layer of the ointment should be applied 2 - 4 times daily to the infected area.
Threolone should not be applied near the eyes.
Patients should be instructed to return to the physician if no improvement in their condition occurs after 4 - 5 days of treatment.

4.3 Contraindications
- Known hypersensitivity to any of the active ingredients or to any of the excipients listed in section 6.1.
- Topical corticosteroids are contraindicated in skin lessions caused by infection with viruses (e.g. herpes simplex, chicken pox), fungi (e.g. candidiasis, tinea) or bacteria (e.g. impetigo).
- This product should not be applied in the external auditory canal of patients with perforated eardrum.
- Because of the chloramphenicol component, patients with a known personal or family history of blood dyscrasias including aplastic anaemia should avoid use of this product.
- This product is not intended for ophthalmic use.
- Patients who have experienced myelosuppression during previous exposure to chloramphenicol.

4.4 Special warnings and precautions for use
For Prednisolone
Long term continuous or inappropriate use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advise is recommended in these cases or other treatment options should be considered.

Visual disturbance
Visual disturbance may be reported with systemic topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use if systemic and topical corticosteroids.

Paediatric population
In infants and children, long-term continuous topical therapy should be avoided where possible, as adrenal suppression can occur even without occlusion. In infants, the napkin may act as an occlusive dressing, and increase absorption.

Any spread of infection requires withdrawal of topical corticosteroid therapy, and systemic administration of antimicrobial agents.

As with all corticosteroids prolonged application to the face is undesirable.

For Choramphenicol
Chloramphenicol toxicity has been reported following chronic exposure.

Discontinue promptly if sensitization or irritation occurs.

The use of chloramphenicol may occasionally result in overgrowth of non-susceptible organisms, including fungi. If any new infection appears during treatment, the antibiotic should be discontinued and appropriate measures taken.

In severe infections the topical use of chloramphenicol should be supplemented by appropriate systemic treatment.

Prolonged or frequent intermittent use of topical chloramphenicol should be avoided, because of the possibility of absorption and of hypersensitivity reactions. It may also increase the likelihood of sensitization and emergence of resistant organisms. Chloramphenicol should be reserved for use only for infections for which it is specifically indicated.

Chloramphenicol does not provide adequate coverage against *Pseudomonas aeruginosa* and *Serratia marcescens*.

Bone marrow hypoplasia, including aplastic anaemia and death, has been rarely reported following topical use of chloramphenicol. Chloramphenicol should not be used when less potentially dangerous agents would be expected to provide effective treatment.

Where the ointment is used on a long-term or intermittent basis, it may be advisable to perform a routine blood profile before therapy and at appropriate intervals thereafter to detect haemopoietic abnormalities.

Fire hazard in contact with dressings, clothing and bedding
Product contains paraffin. Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it

Use in pediatricas
Application of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen.

Excipient with known effect
This medicine contains lanolin anhydrous (wool fat), that may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction
The concomitant administration of chloramphenicol with other drugs liable to depress bone marrow function should be avoided (e.g., azathioprin , chemotherapy)

4.6 Fertility, pregnancy and lactation

Pregnancy
There is inadequate evidence of safety of corticosteroids and chloramphenicol in human pregnancy.
Topical application of corticosteroids to pregnant animals can cause abnormalities of fetal development including cleft palate and intrauterine growth retardation. There may, therefore, be a very small risk of such effects in the human fetus.

Breastfeeding
The safety of topical chloramphenicol in lactation has not been established.
Chloramphenicaol enters the fetal circulation and is distributed into breast milk.

Therefore, this product is not recommended for use during pregnancy and lactation.

4.8 Undesirable effects
For Prednisolone

Eye disorders
Not known (cannot be estimated from the available data): Vision, blurred (see also section 4.4).

Skin and Subcutaneous Tissue Disorders
Not known (cannot be estimated from available data): Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules. (see section 4.4)
If signs of hypersensitivity appear, application should be stopped immediately.

Exacerbation of symptoms may occur.

Local atrophic changes may occur where skin folds are involved, or in areas such as the nappy area in small children, where constant moist conditions favour the absorption of hydrocortisone. Sufficient systemic absorption may also occur in such sites to produce the features of hypercorticism and suppression of the HPA axis after prolonged treatment. The effect is more likely to occur in infants and children, and if occlusive dressings are used.

There are reports of pigmentation changes and hypertrichosis with topical steroids.

For Choramphenicol
The following clinical adverse experiences have been observed with the use of chloramphenicol. More serious side effects (indicated by *) have been reported in patients sensitive to chloramphenicol and are causes for discontinuing the medication.

Blood and Lymphatic System Disorders
Blood dyscrasias, bone marrow depression and rarely aplastic anaemia.

Immune System Disorders
Anaphylactic reaction*, hypersensitivity reaction.

Nervous System Disorders
Burning sensation.

Eye Disorders
Ocular hyperaemia, eye swelling.

Skin and Subcutaneous Tissue Disorders
Angioedema*, urticaria*, rash vesicular and rash maculopapular *, pruritus.

General Disorders and Administration Site Conditions
Local irritation may include subjective symptoms of itching or burning, fever*, sensitivity reactions, pyrexia*.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:
http://sideeffects.health.gov.il

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of Action
Threolone offers the advantages of two active components: chloramphenicol, a powerful broad-spectrum antibiotic, and prednisolone, an anti-inflammatory corticosteroid. Local application of Threolone causes a marked reduction of erythema, desquamation and pruritus, with concomitant elimination of infections caused by chloramphenicol-sensitive organisms.

6. PHARMACEUTICAL PARTICULARS

List of excipients
Petrolatum yellow (Paraffin, yellow soft), lanolin anhydrous (wool fat), mineral oil (paraffin liquid), colloidal solicon dioxide.

Shelf life
The expiry date of the product is indicated on the packaging materials**.**

Special precautions for storage
Store in a dark place below 25°C.

Nature and contents of container
Each pack contains tubes of 10 g ointment.

7 Manufacturer and license holder
Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020

8 Registration Number
027.40.21618

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