Summary of Product Characteristics

Synthomycine 3%
Dermal Ointment

1. NAME OF THE MEDICINAL PRODUCT
Synthomycine 3%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition

Active Ingredient
Chloramphenicol 3%

For the full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM
Ointment.
Yellow ointment.

4.4 Special warnings and precautions for use

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Antibiotic.

Chloramphenicol is effective against certain protozoa, rickettsia and virus-like infections, as well as against many Gram-positive and Gram-negative bacteria. It is useful in the treatment of superficial pyodermas, impetigo, acute folliculitis, seborrhea-like streptodermatitis, and infectious eczematoid dermatitis.

4.2 Posology and method of administration

Direction for use

Patients should be cautioned to report to their physician if no improvement in their condition occurs after 4-5 days of treatment.

Apply to the infected area 3-4 times daily after cleansing.

4.3 Contraindications

Known hypersensitivity to any of the active ingredients or to any of the excipients listed in section 6.1.

Patients with a known personal or family history of blood dyscrasias including aplastic anaemia.

4.4 Special warnings and precautions for use

This medicine is not intended for ophthalmic application.

Chloramphenicol toxicity has been reported following chronic exposure.

Discontinue promptly if sensitization or irritation occurs.

The prolonged use of antibiotics may occasionally result in overgrowth of non-susceptible organisms, including fungi.

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. If any new infection appears during treatment, the antibiotic should be discontinued and appropriate measures taken. 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 local application of chloramphenicol. Chloramphenicol should not be used when less potentially dangerous agents would be expected to provide effective treatment.

Where Chloramphenicol 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.

Excipient with known effect
This medicine contains lanolin (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 medicines liable to depress bone marrow function should be avoided.

4.6 Fertility, pregnancy and lactation

The safety of topical chloramphenicol in pregnanacy and lactation has not been established.
Chloramphenicol enters the fetal circulation and is distributed into breast milk.
Therefore, this medicine is not recommended for use during pregnancy and lactation.

4.8 Undesirable effects

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:
https://sideeffects.health.gov.il

4.9 Overdose
Accidental ingestion of the drug is unlikely to cause any toxicity due to the low content of antibiotic. It is advisable to keep medication out of reach of children. If accidentally ingested by infants or young children, a local Poisons Information Center should be contacted. As there is individual variability in the pharmacokinetics of chloramphenicol in infants and children monitor plasma levels.
Levels exceeding 25 micrograms/mL are frequently considered toxic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of Action

Chloramphenicol is bacteriostatic and possesses a wide range of antibacterial activity. Since it is lipid soluble, it diffuses through the bacterial cell membrane and reversibly binds to the 50 S subunit of bacterial ribosomes, where transfer of amino acids to growing peptide chains is prevented, possibly by suppression of peptidyl transferase activity. This inhibits peptide bond formation and subsequent protein synthesis.

Preparations of chloramphenicol for local treatment are well tolerated.

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

6. PHARMACEUTICAL PARTICULARS

List of excipients
Petrolatum yellow (paraffin, yellow soft), Lanolin (wool fat), Mineral oil (paraffin liquid), Silica, colloidal anhydrous,.

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

Special precautions for storage
Store below 25°C.
The medicine can be used for up to 12 months after first opening, but not after the expiry date.

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

7 Manufacturer and License Holder

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8 Registration Number

025.11.20849

This leaflet was revised in June 2023 according to MoH guidelines.