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 who have experienced myelosuppression during previous exposure to chloramphenicol.

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 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 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 a broad spectrum antibiotic which has activity against many types of Gram-positive and Gram-negative bacteria. Chloramphenicol is not effective against fungi, protozoa, and viruses.

Chloramphenicol is effective against Gram-positive cocci including staphylococci such as *Staph. epidermidis* and some strains of *Staph. aureus,* and streptococci such as *Str. pneumoniae, Str. pyogenes,* and the viridans streptococci.

Gram-negative cocci such as *Haemophilus influenzae* are usually highly sensitive. *Moraxella catarrhalis*, a Gram-negative aerobic diplococcus frequently found as acommensal of the upper respiratory tract, is also highly sensitive.

5.2 Pharmacokinetic properties

Any chloramphenicol that is absorbed will be widely distributed in the body tissues and fluids. It is found in cerebrospinal fluid, giving concentrations of about 50% of those existing in the blood even in the absence of inflamed meninges; it diffuses across the placenta into the fetal circulation, into breast milk and into the aqueous and vitreous humour of the eye; it is also secreted in saliva, with the highest concentrations occurring in the kidneys and liver. Up to about 60% in the circulation is bound to plasma protein.

Chloramphenicol is excreted mainly in the urine as the glucuronide with small amounts being excreted via the bile and faeces. It has a reported half-life of 1.5 to 4 hours which is increased in patients with liver impairment and neonates to between 24 and 28 hours in the latter.

Renal impairment has relatively little effect on the half-life of the active drug, due to its extensive metabolism, but may lead to accumulation of the inactive metabolites.

The absorption, metabolism, and excretion of chloramphenicol are subject to considerable interindividual variation, especially in infants and children, making monitoring of plasma concentrations necessary to determine pharmacokinetic in a given patient.

5.3 Preclinical safety data

No additional data of relevance to the prescriber.

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

Teva Israel Ltd.,

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8 Registration Number
025.11.20849

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