

# 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 should avoid use of this product

#### **4.4 Special warnings and precautions for use**

This medicine is not intended for ophthalmic application.

Discontinue promptly if sensitization or irritation occurs.

The prolonged use of antibiotics may occasionally result in overgrowth of non-susceptible organisms, including fungi. If new infections appear during medication, treatment should be discontinued, and appropriate measures taken.

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**

Systemically absorbed forms of chloramphenicol enter the fetal circulation and are distributed into breast milk. If given systemically to the mother shortly before parturition or whilst breastfeeding, chloramphenicol may cause bone marrow suppression of the neonate or the “grey baby syndrome”, characterized by cyanosis and hypothermia, owing to the limited glucuronidating capacity of the newborn infant's liver. 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 have been reported in association with the use of chloramphenicol.

#### *Immune System Disorders*

Anaphylactic reaction\*, hypersensitivity, reaction to drug excipients.

#### *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\*, similar sensitivity reactions to other materials in topical preparations also may occur, 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**

Teva Israel Ltd.,  
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## **8 Registration Number**

025.11.20849

**This leaflet was revised in December 2022 according to MoH guidelines.**