

“פורמט עלון זה נקבע ע”י משרד הבריאות ותוכנו נבדק ואושר”. עלון מאושר : נובמבר 2011
“This leaflet format has been determined by the Ministry of Health and the content thereof
has been checked and approved.” Date of approval: November 2011.

SYNTHOMYCINE

SKIN OINTMENT

Composition

Active Ingredient

Chloramphenicol (micronized) 3%

Other Ingredients

Petrolatum yellow (yellow Vaseline), lanolin, mineral oil (paraffin oil), silica colloidal anhydrous,.

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.

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.

Contraindications

Known hypersensitivity to chloramphenicol or to any other ingredient of the preparation.

Patients with a known personal or family history of blood dyscrasias including aplastic anaemia should avoid use of this product.

Warnings

This preparation is not intended for ophthalmic application.

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.

Use in 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 product is not recommended for use during pregnancy and lactation.

.Adverse Reactions

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*.

Precautions

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.

Drug Interactions

The concomitant administration of chloramphenicol with other drugs liable to depress bone marrow function should be avoided.

Directions 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.

Overdosage

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.

Presentation

Aluminium tubes of 10 g.

Storage

Store below 25°C.

Registration Number:

025.11.20849.00

Manufacturer

Teva Pharmaceutical Industries Ltd

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For

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