PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Synthomycin 3%

Skin ointment

Composition

Chloramphenicol 3%

For information regarding inactive ingredients and allergens, see section 2 "Important information about some of the ingredients of the medicine" and section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

For treating superficial skin infections caused by microorganisms sensitive to chloramphenicol.

Therapeutic class

Topical antibacterial.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to chloramphenicol or to any of the other ingredients this medicine contains (see below in the section "Important information about some of the ingredients of the medicine" and section 6 "Additional information").
- You or any of your family members have a history of anemia, bleeding or other blood problems.

Special warnings regarding the use of the medicine

Before treatment with the medicine, tell the doctor if you have or have had in the past impaired bone marrow function.

This preparation contains chloramphenicol, which may cause changes in the blood profile upon prolonged use. Therefore, prolonged use of the preparation should be avoided.

The preparation is not intended for use in the eyes, do not allow the preparation to come into contact with them. In case of contact with the eyes, wash them immediately with water.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially if you are taking medicines that suppress the bone marrow function (medicines that may cause a decrease in red blood cells, white blood cells or platelets).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, do not use the medicine without consulting a doctor before starting the treatment.

Important information about some of the ingredients of the medicine

The medicine contains the ingredient Lanolin, which may cause skin irritation (e.g., contact dermatitis).

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The dosage and treatment regimen will be determined only by the doctor.

Standard dosage when no other instruction from the doctor is given:

Apply a small amount of the ointment on the affected area, 3-4 times a day.

Do not exceed the recommended dose.

If there is no improvement in your condition within a few days, contact the doctor again.

Please note

Do not swallow! This medicine is intended for external use only.

If you have accidentally swallowed the medicine

If you have swallowed or if a child has swallowed the ointment, refer immediately to the doctor or to a hospital emergency room and bring the package of the medicine with you.

If you have forgotten to use the medicine

If you have forgotten to apply the ointment at the scheduled time, apply it when you remember, and continue with the treatment as you were instructed by the doctor.

Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose <u>every time</u> you take the medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Synthomycin 3% may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

If the following side effects occur, contact the doctor immediately:

Allergic reactions, including: fever, rash, swelling of the face, lips, mouth sores or sore throat that cause swallowing or breathing difficulties, swelling of the hands, feet or ankles.

If the following side effects occur, stop the treatment and contact the doctor:

Reduced blood count, which manifests in fever, sore throat, tiredness, bleeding, weakness or a hypersensitivity reaction, which manifests in local redness, irritation, rash, itch, swelling or inflammation (which were not present before using the preparation), bleeding or bruising easily.

If after the end of the treatment the following side effects occur for the first time, contact the doctor immediately:

Fever, sore throat.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (Exp. Date) appearing on the package. The expiry date refers to the last day of that month.

Store below 25°C.

Do not discard medicines in wastewater or domestic trash. Ask your pharmacist how to discard medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, the medicine also contains:

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

What does the medicine look like and what are the contents of the package:

Each package contains a tube containing 10 grams of yellow ointment.

Name and address of marketing authorization holder and manufacturer:

Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.

Registration number of the medicine in the national drug registry of the Ministry of Health:

025.11.20849

The leaflet was revised in January 2022 in accordance with the Ministry of Health guidelines.

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