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

The medicine is dispensed with a doctor's prescription only

# Hycomycin

Skin ointment

Composition

Hydrocortisone 2.5% Neomycin Sulfate 0.5%

For information regarding inactive ingredients and allergens, see section 2 under "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 the treatment of infectious inflammations of the skin

#### Therapeutic class

Hydrocortisone: Corticosteroid

Neomycin Sulfate: Aminoglycoside antibiotic

#### 2. Before using the medicine Do not use this medicine if:

- You have a known sensitivity to any of its ingredients or to any other medicines from the aminoglycoside group.
- You suffer from fungal infections, tuberculosis of the skin, herpes simplex or chickenpox.
- As with any external preparations containing neomycin, do not use this medicine to treat external ear inflammation if there is a perforated

# Special warnings regarding the use of the

Do not use the preparation for any purpose other than that for which it was prescribed.

Do not use this medicine on extensive skin areas or open wounds, unless specifically instructed by the doctor

Do not allow the preparation to come into contact with eyes. In case of contact wash immediately with water. Before treatment with Hycomycin, inform the doctor if:

- You are pregnant or breastfeeding
- You suffer or have suffered in the past from impaired function of the immune system, diabetes, kidney problems, dizziness, hearing problems or hearing loss, ringing in the ears

### Children and adolescents

Special caution is required when used on children and adolescents. Use in these age groups must be accompanied by medical supervision.

#### 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.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, consult the doctor before starting the treatment.

#### Important information about some of the ingredients of the medicine

The medicine contains the ingredient lanolin (Lanolin anhydrous), which may cause skin irritation (such as contact dermatitis).

The medicine contains the ingredient methylparaben (Methyl p-hydroxybenzoate (E218)), that may cause allergic reactions (possibly delayed).

# 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

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

- If there is no improvement in your condition within a week or if your condition worsens, contact the doctor again.
- Do not use the preparation to treat infants and children under 4 years of age for more than 3 weeks, especially on areas covered by diapers.
- Unless indicated by the doctor, occlusive dressing of the infected area should be avoided. (Plastic diapers are considered an occlusive dressing).

This medicine should be used at set intervals as determined by the treating doctor.

#### Do not exceed the recommended dose.

#### Method of use

Do not swallow, for external use only.

Avoid contact with eyes or with mucous membranes (such as the mouth and nose) (see warnings in section 2)

If you took an overdose or if a child accidentally swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

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 every time 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 Hycomycin ointment may cause side effects. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Stop the treatment and contact the doctor immediately if any of the following side effects occurs:

- Local irritation, rash or inflammation (that were not present before using the preparation)
- Swelling of the face, lips, tongue or other parts of the body
- Shortness of breath or difficulty breathing, wheezing (rare)

#### Other side effects that may occur

Redness, swelling, dryness, a localized feeling of warmth and tingling, failure to cure.

These side effects usually pass within a short time after the period of adapting to the preparation. However, if these side effects persist and/or are bothersome, refer to the doctor

Repeated treatment with the preparation for a long period of time may cause changes in hair growth and in skin color, appearance of stretch marks on the skin and bulging of veins, worsening of infections. In these cases, stop the treatment and refer to the doctor immediately.

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 this medicine in a dry place, 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:

White petrolatum, Mineral oil, Lanolin anhydrous, Paraffin hard, Super harlotan woolwax alcohols, Methylparaben, Butylparaben.

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

Each package contains a tube with 15 grams of white-yellowish ointment.

Name and address of marketing authorization holder and manufacturer

Teva Israel Ltd..

124 Dvora HaNevi'a St., Tel Aviv 6944020

This leaflet was revised in June 2022 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 051-45-24387

Hycomycin PIL MW0622

