

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Hycomycin
Skin ointment**Composition**

Hydrocortisone 2.5%

Neomycin sulfate 0.5%

For information about inactive ingredients and allergens see section 2 under – 'Important information about some of this medicine's ingredients', and section 6 – 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

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

1. WHAT IS THIS MEDICINE INTENDED FOR?

Used to treat of inflammatory skin infections.

Therapeutic group

Hydrocortisone: corticosteroid

Neomycin sulfate: an aminoglycoside antibiotic

2. BEFORE USING THIS MEDICINE**Do not use this medicine if:**

- You are sensitive (allergic) to hydrocortisone, neomycin sulfate, other aminoglycoside medicines or to any of the other ingredients that this medicine contains, which are listed in section 6.
 - You have viral infections, such as cold sores, herpes or chicken pox
 - You have fungal infections, such as athlete's foot, ringworm, or thrush
 - You have skin blisters or sores that are caused by a bacterial infection, such as impetigo, tuberculosis of the skin
 - Like all medicinal products for external use that contain neomycin, do not use this medicine for inflammation of the outer ear if the eardrum is perforated.
- If any of the above conditions apply to you, consult your doctor or pharmacist.

Special warnings regarding use of this medicine

Do not use this medicine on large areas of skin or on open sores unless your doctor tells you to.

Do not allow this medicine to come into contact with your eyes. In case of contact, rinse with water immediately.

Before using Hycomycin, tell your doctor if:

- you are applying the ointment under an airtight dressing, including a child's nappy. These dressings make it easier for the active ingredient to pass through the skin and can cause an overdose.
- you have kidney problems; your doctor may decide to change the amount or number of times you apply the ointment
- you have or have ever had hearing problems, hearing loss, ringing in your ears, dizziness

If there is a worsening of your condition during use, consult the doctor who prescribed the medicine – you may be experiencing an allergic reaction, or your condition requires a different treatment.

If your condition reverts to what it was before treatment, shortly after stopping treatment—within 2 weeks—do not go back to using the ointment without consulting the doctor who prescribed it, unless this doctor has previously advised you to do so.

If your condition reverts to what it was before treatment after completing the treatment, and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please consult your doctor before restarting treatment.

This ointment contains paraffin. Fabric (clothing, bedding, dressings, etc.) that has been in contact with this product may catch fire and burn more easily. Do not smoke or go near naked flames because there is a risk of severe burns. Washing the fabric may reduce the risk but not totally remove it.

If you are not sure if any of these warnings apply to you, consult your doctor or pharmacist before using this medicine.

Children and adolescents

Special caution is required when using in children and adolescents. Use in these ages requires medical supervision.

Interactions with other medicines

If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist.

If this ointment is absorbed into the body in large amounts, the neomycin component could extend or increase the effects of medicines used to relax muscles during surgery. If you are having surgery you should tell the doctor that you have used this ointment.

Pregnancy and breastfeeding

Using this medicine during pregnancy and breastfeeding is not recommended.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

This ointment is unlikely to affect your ability to drive or operate machinery.

Important information about some of this medicine's ingredients

This medicine contains the ingredient lanolin (lanolin anhydrous) which can cause skin irritation (such as contact dermatitis).

This medicine contains the ingredient methyl paraben (methyl p-hydroxybenzoate (E218)) which can cause allergic reactions (possibly delayed).

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

- If your condition does not improve within one week or if it gets worse, talk to your doctor again.
- Do not use this medicine on babies and children under 4 years old for longer than 3 weeks, particularly on areas that are covered by a nappy (diaper).
- Unless the doctor indicated otherwise, avoid using an airtight dressing on the affected area (plastic nappies are an airtight dressing).

Apply this medicine at regular times, as prescribed by your doctor.

Do not exceed the recommended dose.

Using this medicine

Do not swallow, for external use only.

Do not let the ointment get into your eyes or mucous membranes (like your mouth and nose) (see in section 2 'Special warnings regarding use of this medicine').

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forgot to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor. Follow the treatment as recommended by your doctor.

Even if there is an improvement in your health, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, using Hycomycin ointment may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop the treatment and contact your doctor immediately if you get any of the following side effects

- your skin problem gets worse or your skin becomes swollen during treatment; you may be allergic to the medicine or need other treatment

Other side effects you may notice when using this ointment

- irritation or itching where the ointment is applied
- increased hair growth and change in skin colour

Side effects if you use this ointment for a long time, or you use a lot each time you apply it, or you apply it under an airtight dressing or a nappy

- thinning of your skin that may also damage more easily
- weight gain, rounding of the face, and high blood pressure. These are more likely to happen in infants and children.

Steroid withdrawal symptoms: If used continuously for prolonged periods withdrawal symptoms may occur on stopping treatment, including: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects due to Medicinal Treatment' found on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects. You can also use this link <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and all other medicines should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) which appears 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 dispose of any medicine via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. ADDITIONAL INFORMATION

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

white petrolatum, mineral oil, lanolin anhydrous, paraffin hard, Super Harlotan wool wax alcohols, methylparaben, butylparaben.

What the medicine looks like and contents of the package:

Within each carton is a tube which contains 15 grams of yellowish-white homogenous ointment.

Name and address of the license holder, manufacturer:

Teva Israel Ltd.,
124 Devora HeNevi'a St., Tel Aviv 6944020.

This leaflet was revised in March 2023 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

051-45-24387

For further information about the medicine and for updated patient leaflets in English, Hebrew and Arabic, please scan the following code:



<https://israeldrugs.health.gov.il/#!/medDetails/051%2045%2024387%2000>

You may contact the license holder for a printed leaflet in English at:
Tevacare@med-trix.com or by telephone: 1-800-805-005