



**PATIENT PACKAGE INSERT IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The dispensing of this medicine requires a doctor's prescription

Read this package insert carefully in its entirety
before using this medicine

The format of this leaflet was determined by the Ministry
of Health and its content was checked and approved

OTOMYCIN®

Ear Drops

Composition:

Neomycin (as sulphate)	0.35%
Phenylephrine HCl	0.25%
Sodium propionate	5.00%
Benzocaine	3.00%

Inactive ingredients:

Purified water, propylene glycol, PEG 400, glycerin, benzyl alcohol, propionic acid, sodium metabisulphite.

Therapeutic group:

Neomycin (as sulphate) is an aminoglycoside antibiotic.
Phenylephrine HCl is a sympathomimetic.

Sodium propionate is an antifungal.

Benzocaine is a topical anesthetic.

Therapeutic activity:

Topical treatment of otitis externa and otitis media caused by bacteria and/or fungi.

When should the preparation not be used?

This medicine should not be used by patients with perforated eardrum.

Do not use this medicine if you are sensitive to any of its ingredients.

Do not take this medicine without consulting a doctor before starting treatment:

If you are pregnant or breastfeeding.

If you are suffering, or have suffered in the past, from impaired function of the kidney/urinary tract, aural disease.

Warnings:

Do not use this medicine frequently, or for a long period, without consulting a doctor.

If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

Drug interactions:

If you are taking another drug concomitantly or if you have just finished treatment with another medicine, inform the attending doctor, in order to prevent hazards or lack of efficacy arising from drug interactions.

Side effects:

In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine, for example: itching or burning. These side effects usually disappear within a short time following the period of adaptation to the medicine.

Effects that require special attention:

Those indicating hypersensitivity to the medicine such as: redness, skin rash, itching: stop treatment and consult a

physician. In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

Adverse reactions and drug interactions in children and infants:

Parents must inform the attending doctor about any side effects, as well as any additional medicine being taken by the child!

Dosage:

Dosage is according to doctor's instructions only.
If there is no improvement in your condition within 7 days, refer to your doctor. This medicine is to be taken at specific time intervals as determined by the attending doctor.

Attention:

Do not swallow! This medicine is intended for use in the ears only. Avoid contact between this medicine and the eyes.

Directions for use:

Wash your hands. Lie down or tilt your head to the side, so that the ear to be treated faces upward.

In adult patients: Gently grasp the ear lobe and pull it upwards and backwards to straighten the ear canal.

In pediatric patients: Gently grasp the ear lobe and pull it downwards and backwards to straighten the ear canal.

Instil drops of the medicine into ear and maintain the adopted position for a few minutes in order to allow the medicine to reach the interior of the ear.

To prevent contamination of the ear drops: Take care not allow the bottle tip or the dropper tip to come into contact with any surface, including the hands or the ear itself. Do not rinse the dropper after use! Wipe the tip of the dropper with a clean paper tissue and close the bottle tightly.

How can you contribute to the success of the treatment?

Complete the full course of treatment as instructed by the doctor. Even if there is an improvement in your health, do not discontinue use of this medicine before consulting your doctor.

Avoid poisoning!

This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

Do not induce vomiting unless explicitly instructed to do so by a doctor! This medicine has been prescribed for the treatment of your ailment; in another patient it may cause harm. Do not give this medicine to your relatives, neighbours or friends.

Do not take medicines in the dark!
Check the label and the dose each time you take your medicine.

Wear glasses if you need them.

Storage: Store below 25°C. Do not refrigerate.

Shelf life after opening the preparation: 2 months.

Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you. Do not store different medications in the same package.

License number: 1586.24749

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