

**PATIENT PACKAGE INSERT ACCORDING TO
PHARMACISTS' REGULATIONS (PREPARATIONS)-1986**

This medicine can be sold without a physician's prescription

OTIDIN[®] TEVA* EAR DROPS

*** Alternate formula**

Composition: Each 1 ml contains:

Phenazone 5.0%

Amethocaine HCl 0.5%

Inactive ingredients: see section 6 "Additional information".

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

Take this medicine according to the instructions in section 3 "How to use this medicine?" in the leaflet.

Consult your pharmacist if you need additional information. Refer to a doctor if the symptoms of your illness get worse or if they do not improve after 2-3 days.

1. What is the medicine intended for?

The medicine is intended for the relief of pain in acute otitis media and the external, auditory canal.

Therapeutic group:

Phenazone- pyrazolone derivative, analgesic and anti- inflammatory.

Amethocaine HCl- local anaesthetic.

2. Before using the medicine:

Do not use the medicine if:

Do not use this medicine if you are sensitive to any of its ingredients or if you suffer from perforated ear drum membrane.

If you are not sure whether you should use this medicine, talk to your doctor or pharmacist.

Special warnings concerning the use of this medicine

Before starting treatment with Otidin Teva, tell your doctor if you are suffering or have suffered in the past from:

Sensitivity to any type of food or medicine.

Do not use this medicine frequently or for long periods of time without consulting a doctor.

Drug interactions

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

3. How to use this medicine?

Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The usual recommended dosage for adults and children is:

Instill a sufficient amount to fill the ear canal 3-4 times a day.

Do not exceed the recommended dosage.

This medicine is for external use only.


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.

Method of administration:

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.

If the patient is a child: gently grasp the ear lobe and pull it downwards and backwards



to straighten the ear canal. Instill drops of the medicine into the ear and maintain the adopted position for a few minutes, in order to allow the medicine to reach the interior of the ear. A clean cotton-wool plug may be inserted into the opening of the ear (not deeply) to prevent the medicine from leaking out.

To prevent contamination - take care not to allow the bottle tip or the dropper tip to come into contact with any surface (including the hands and 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.

The medicine may be warmed to body temperature by holding the bottle in the hand for a few minutes.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of **Otidin Teva** may cause side effects in some users. In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine.

Side effects that require special attention: In case of local irritation, stop treatment and refer to a doctor. In any case you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

If a side effect appears, if one of the side effects worsen or if you suffer from a side effect which is not mentioned in this leaflet, consult your doctor.

Adverse reactions and drug interaction in children and infants: Parents must inform the attending doctor about any side effect, as well as any additional medicine being taken by the child!

For further information see sections "Side effects" and "Side effects that require special attention", mentioned above.

Side effects can be reported to the Ministry of Health by clicking on the link "Report adverse effects and problems associated with medications and drugs" on the home page of the Ministry of Health website (www.health.gov.il) which refers to the online form for reporting adverse effects or by clicking on the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants, 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) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C. Can be used for up to 3 months after the bottle is first opened, and not later than the expiry date that appears on the package.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away 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: Glycerin.

What the medicine looks like and what the package contains:

Otidin Teva: clear, colorless solution.

Approved package size: 10 ml in a bottle.

Manufacturer and registration holder: Vitamed Pharmaceutical Industries Ltd., 6 Hatahana St., P.O.B. 114, Binyamina 3055002, Israel.

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Drug registration number at the national drug registry of the Ministry of Health:
165-07-36421-00