Patient package insert in accordance with
the Pharmacist's Regulations (Preparations) – 1986
This medicine is dispensed with a doctor's prescription only.

***Alternate formula**
DEX-OTIC® TEVA* Ear Drops
Composition: Each 1 ml contains:
Dexamethasone Sodium Phosphate 1 mg
Neomycin Sulfate 5 mg
Polymyxin B Sulfate 10,000 I.U.
Inactive ingredients: See Section 6 – Additional Information.
Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to a doctor or pharmacist.
This medicine was prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

1. What is the medicine intended for?

Treatment of superficial infections of the outer ear caused by bacteria susceptible to the medicine.
Therapeutic group:
Dexamethasone Sodium Phosphate has anti-inflammatory activity.
Neomycin Sulfate and Polymyxin B Sulfate have anti-bacterial activity.

2. Before using this medicine

! Do not use this preparation if:

- You are sensitive (allergic) to the active ingredients or to any of the medicine's other ingredients.
- In cases of a perforated eardrum, or a suspected perforated eardrum.

! Before using Dex-Otic Teva tell your doctor if:
• You are pregnant or breastfeeding.
• You are suffering, or have suffered in the past, from impaired hearing, herpes simplex (HSV), chicken pox, chronic herpes of the ear or tuberculosis of the ear, viral or fungal infections of the skin or the ear; if you are suspected or known to be suffering from a perforated eardrum; or in cases of chronic ear infections.
! Special warnings regarding the use of this medicine:
• If you are sensitive to any type of food or medicine, such as aminoglycosides, polymyxin or sulfites, you must inform your doctor before taking this medicine.
• Prolonged use or the use of a high dose of this medicine on open wounds or injured skin may cause deafness. This is especially important in the case of children.
• Do not swallow. If the medicine has been swallowed, especially by a child, refer immediately to a doctor or to a hospital emergency room.
! If you are taking, or if you have recently taken other medicines, including non-prescription medicines and food supplements, inform your doctor or pharmacist.
! Pregnancy and breastfeeding
Consult your doctor if you are pregnant, attempting to conceive, or breastfeeding.

3. How should this medicine be used?

This medicine must always be used according to a doctor's instructions.
You must consult a doctor or pharmacist if you are unsure.
The dosage and the method of treatment will be determined by a doctor only.
The recommended dosage is usually:
2-3 drops in the ear, 3-4 times a day.
Dosage for children: 1-2 drops in the ear, 3-4 times a day.
Do not exceed the recommended dosage.
If there is no improvement in your condition within 7 days, consult a doctor.
Instructions for use: Wash your hands. Lie down or tilt your head so that the ear being treated is turned upwards. Drip the medicine into the ear and remain in this position for several minutes, to enable the medicine to reach inside the ear. To prevent contamination, make sure that the tip of the dropper does not come into contact with any surface. Do not wash the dropper. Wipe the tip with a clean napkin and close the bottle tightly.
Attention! Do not swallow! For external use only. This medicine is not intended for use in the eyes.
If you have accidentally taken an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the medicine package with you.
I**f you forget to take this medicine at the appropriate time,** do not take a double dose. Take the next dose at the regular time and consult a doctor.
If you have further questions regarding the use of this medicine, consult a doctor or pharmacist.

4. Side effects

As with any medicine, the use of **Dex-Otic Teva** may cause side effects in some users. Do not be alarmed by the list of side effects. You may not experience any of them.
Stop using the medicine and contact a doctor immediately if you feel:
Sensitivity or allergic reactions (irritation or a rash).
Additional side effects:
A temporary tingling or burning sensation.
If you experience a side effect, if any of the side effects worsens, or if you experience side effects not mentioned in this leaflet, consult a doctor.
Side effects can be reported to the Ministry of Health by clicking the link "Report of side effects due to medications" on the home page of the Ministry of Health website (www.health.gov.il), which will open an online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. How should this medicine be stored?

• **Avoid poisoning!** This medicine, and all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, to prevent poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
• Do not use the medicine after the expiry date stated on the package. The expiry date refers to the last day of that month.
• Storage conditions: Store below 25°C.
• Even under the recommended packaging and storage conditions, medicines may only be kept for a limited period of time. Please note the expiry date of the preparation! In case of doubt, consult the pharmacist who dispensed the medicine to you. Do not store different medicines in the same package.
• Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.
• The medicine may be used for up to 6 months after the bottle is first opened, and not later than the expiry date that appears on the package.

6. Additional information

In addition to the active ingredients, this medicine also contains: Sodium Citrate, Methylparaben Sodium, Sodium Metabisulfite, Propylene Glycol, Propylparaben Sodium, HCl dilute, Purified Water.
What the medicine looks like and what the package contains:
A white plastic bottle containing a clear to yellowish watery solution.
A dropper is attached to the top of the bottle, covered by a white plastic screw cap.

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