Patient package insert according to
Pharmacists' Regulations (Preparations)- 1986
This medicine can be sold with a physician's prescription only

DEX-OTIC® TEVA, EAR DROPS

Each 1 ml contains:
Dexamethasone (as Sodium Phosphate) 1 mg
Neomycin (as Sulfate) 5 mg
Polymyxin B Sulfate 10,000 I.U.

Inactive ingredients and allergens in the medicine- see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same as yours.

1. What is the medicine intended for?

For the treatment of superficial bacterial infections of the external auditory ear canal, caused by organisms susceptible to the medicine.

Therapeutic group:
Dexamethasone (as Sodium Phosphate)- Synthetic glucocorticoid.
Neomycin (as Sulfate)- Aminoglycoside antibiotic.
Polymyxin B Sulphate- Polymyxin antibiotic.

2. Before using this medicine

Do not use this medicine if:

- You are hypersensitive (allergic) to the active ingredient/s [Dexamethasone (as Sodium Phosphate), Neomycin (as Sulphate), Polymyxin B Sulphate] or to any of the other ingredients this medicine contains (see section 6 "Additional information").
- You are hypersensitive (allergic) to aminoglycoside antibiotics such as Framycetin, Kanamycin or Gentamicin.
- You have a perforated ear drum.
- You have either a viral, fungal or tubercular (TB) infection.

Do not use if one or more of the above conditions apply to you. If you are not sure, consult your doctor or pharmacist before using the medicine.

Special warnings regarding the use of this medicine
Before using Dex-Otic Teva, tell the doctor if:
- You have kidney problems. Your doctor may change how often you use **Dex-Otic Teva**.
- You have a long-standing infection of your outer ear.
- You know or think you have a mitochondrial disease (mutations in parts of the cell which help make energy); certain mitochondrial diseases may increase your risk of hearing loss with the use of this medicine.

If you are not sure if any of the above apply to you, consult your doctor or pharmacist before using **Dex-Otic Teva**.

Conditions you need to look out for
Contact your doctor as soon as possible if you get an inflammation of the large intestine, causing watery diarrhoea, usually with blood and mucus, stomach pain and/ or fever.

If you are due to have surgery
Tell your doctor you have used **Dex-Otic Teva** if you are due to have surgery. If **Dex-Otic Teva** is absorbed into the body in large amounts, the effects of medicines used to relax muscles during surgery can last longer or these effects could be stronger.

Drug interactions:
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Do not use **Dex-Otic Teva** with antibiotics such as Framycetin, Kanamycin or Gentamicin, or other Aminoglycosides. Using them at the same time may increase the risk of hearing, nerve and kidney damage.

Pregnancy and breastfeeding:
Do not use **Dex-Otic Teva** if you are pregnant or plan to get pregnant.
Do not breastfeed while using **Dex-Otic Teva**.
Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant or breastfeeding.

Important information about some of the ingredients of this medicine
Dex-Otic Teva contains 250 mg of Propylene Glycol in each 1 ml, which is equivalent to 250 mg/ ml.

3. How to use this medicine?

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.
The dosage and manner of treatment will be determined by the doctor only.
The usual dosage is generally:
In adults: 2-3 drops into the ear, 3-4 times a day.
In children: 1-2 drops into the ear, 3-4 times a day.
Do not exceed the recommended dose.
Duration of treatment-
If there is no improvement within your condition in 7 days, refer to the doctor.
Method of administration:
Do not swallow! for external use only. This medicine is not intended for treatment of the eyes.
Instructions for use:

1. Wash your hands thoroughly before using the medicine.
2. Lie down or tilt your head to the side, so that the ear to be treated faces upward.
3. Instill drops of the medicine into the ear and maintain this position for a few minutes, in order to allow the medicine to reach the interior of the ear.
4. To prevent contamination of the medicine, take care not to allow the bottle lip to come into contact with any surface.
5. Do not rinse the dropper. Wipe the tip of the dropper with a clean tissue and close the bottle tightly.

If you have accidentally taken a higher dosage
If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine
If you forgot to take the medicine at the designated time, take a dose as soon as you remember and take the next dose at the usual time.
Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> 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. <u>Side effects</u>

As with any medicine, the use of **Dex-Otic Teva** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
Stop taking this medicine and refer to the doctor immediately with the appearance of one or more of the following serious side effects:
• Rarely, an allergic reaction to the medicine can occur. Your ear infection may:
- Seem to get worse instead of better.
- Become red, scaly and itchy with swelling. This may be due to your skin not healing properly.
• You may get a stinging or burning sensation when using the drops. This could mean you have a perforated ear drum.

If you use the medicine in large quantities, it may affect your hearing, nerves and kidneys, but it is unlikely that such an effect will occur when using the regular dose of the medicine.

Additional side effects:
Rare side effects (effects that appear in 1-10 out of 10,000 users):
• Headache.
• Flaking skin in areas where you have applied the medicine.
• Thinning of the skin, which may bruise easily.
• Red spots on your skin that may appear "spidery".
• Lines on your skin that look like stretch marks.
• Existing skin conditions such as eczema getting worse.
If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Report of side effects
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 Ministry of Health home page (<u>www.health.gov.il</u>), which links to an online form for reporting side effects, or by following the link: <u>https://sideeffects.health.gov.il</u>

5. <u>How to store the medicine?</u>

• 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) that appears on the package. The expiry date refers to the last day of that month.
• **Storage conditions:**
  - Store below 25°C.
  - The medicine can 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.
• Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. <u>Additional information</u>

In addition to the active ingredients, this medicine also contains:
Propylene Glycol, Sodium Citrate, Methylparaben Sodium, Sodium Metabisulfite, Propylparaben Sodium, HCl dilute, Purified

Water.
What the medicine looks like and what the package contains:
A bottle containing a clear colorless to straw color (yellowish) solution.
Approved package size: 5 ml.

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:
165-10-36420-00