

**Patient package insert according to
Pharmacists' Regulations (Preparations)- 1986**
This medicine can be sold without a physician's prescription

ANAESTHETIC, Ear Drops

Composition:

Phenazone 5% W/W, Tetracaine Hydrochloride 0.5% W/W.

Each 1 ml contains: 50 mg Phenazone and 5 mg Tetracaine Hydrochloride.

Inactive ingredients and allergens in the medicine- see section 6 "Additional information".

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.

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

Tetracaine Hydrochloride- Local anaesthetic.

2. Before using this medicine

Do not use this medicine if:

- You are hypersensitive (allergic) to the active ingredients (Phenazone and/ or Tetracaine Hydrochloride) or to any of the other ingredients this medicine contains (see section 6 "Additional Information").
- You are hypersensitive (allergic) to other similar types of local anaesthetic.
- You are taking medicines used to treat bacterial infection or diabetes of the "Sulphonamides" class.
- You have a perforated (burst) ear drum.
- Do not use this medicine in premature babies.

Special warnings regarding the use of this medicine

- Do not use this medicine frequently or for a prolonged period.
- If there is an infection present, consult your doctor.

Drug interactions:

If you are taking or have recently taken other medicines, including nonprescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- "Sulphonamides" class medicines, used to treat bacterial infection or diabetes.
- Accidental swallowing of the medicine may affect the metabolism of medicines broken down by liver enzymes. Little absorption is expected from topical application into the ear canal.

Pregnancy and breastfeeding:

Safety for use in pregnancy and breastfeeding has not been established.

If you are pregnant, think you may be pregnant or are breastfeeding, consult the doctor or pharmacist before using the medicine.

Driving and using machines:

Anaesthetic is not expected to affect your ability to drive or use machines.

3. How to use this medicine?

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

For adults and children, the usual dosage is generally: Instill a sufficient amount to fill the ear canal 3-4 times daily. Refer to a doctor if the symptoms of your illness get worse or if they do not improve after 2-3 days.

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

Do not exceed the recommended dose.

Method of administration:

Do not swallow! This medicine is intended for external use only.

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

4. To prevent contamination of the solution, take care not to allow the bottle lip or the dropper tip to come into contact with any surface, including the hands and the ear itself.

5. Do not rinse the dropper after use! Wipe the tip of the dropper with a clean paper 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 this medicine at the designated time, take a dose as soon as you remember and take the next dose at the usual time.

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 regarding the use of this medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of **Anaesthetic** 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.

Side effects of unknown frequency (effects for which a frequency has not yet been determined):

- Skin eruptions and hypersensitivity (allergic) reactions.
- Itching, discomfort and/ or soreness around the ear canal.

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 (www.health.gov.il), which links to an online form for reporting side effects, or by following 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) 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 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 protect the environment.

6. Additional information

In addition to the active ingredients, the medicine also contains: Glycerin.

What the medicine looks like and what the package contains: A bottle containing a clear, colorless to slightly yellow solution.

Approved package size: 10 ml.

Manufacturer and registration holder:

Vitamed Pharmaceutical Industries Ltd., 6 Hatahana St., P.O.B. 114, Binyamina 3055002, Israel.

Revised in September 2023 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:

063-15-28051-00