Prescribing Information

1 NAME OF THE MEDICINAL PRODUCT

Anaesthetic

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of solution contains: Phenazone 50 mg (5% w/v) and Tetracaine hydrochloride 5 mg (0.5% w/v).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ear drops, solution

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Anaesthetic is indicated for the relief of pain in acute otitis media and the external, auditory canal.

4.2 Posology and method of administration

Route of administration: For auricular use. The medicine should not be swallowed.

Recommended Dosage Schedule:
Adults and children: the usual dosage is generally: Instill a sufficient amount to fill the ear canal 3-4 times daily. If the symptoms get worse or if they do not improve after 2-3 days, the patient should contact a doctor. The medicine may be warmed to body temperature by holding the bottle between the hands for a few minutes.

4.3 Contraindications

Hypersensitivity to the active substances Phenazone and/or Tetracaine hydrochloride or to any of the excipients listed in section 6.1.
Hypersensitive to other similar types of local anaesthetic.
Tetracaine is hydrolysed in the body to p-amino-benzoic acid and should not therefore be used in patients being treated with sulphonamides.

In view of the immaturity of the enzyme system which metabolises the ester type local anaesthetics in premature babies, Tetracaine should be avoided in these patients.

Anaesthetic should not be used in patients who have perforated eardrums.

4.4 Special warnings and precautions for use

This medicine should not be use frequently or for a prolonged period.
If improvement does not occur within 24 hours the doctor should be consulted.
If infection is present the doctor should be consulted.

4.5 Interaction with other medicinal products and other forms of interactions

Oral phenazone affects the metabolism of drugs broken down by liver enzymes. However, little absorption is expected from topical application into the auditory canal.
Anaesthetic should not be used in patients being treated with sulphonamides (see section 4.3 above)

4.6 Pregnancy, lactation and fertility

Safety for use in pregnancy and lactation has not been established. There is no information to contraindicate the use of Anaesthetic during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Side effects of unknown frequency (effects for which a frequency has not yet been determined):
Phenazone may give rise to skin eruptions and hypersensitivity reactions.
Tetracaine may give rise to dermatitis in hypersensitive patients.
Itching, discomfort and/or soreness around the ear canal.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic classification (Group + ATC code): Analgesic and Antipyretic: S0ZDA03.
Phenazone has analgesic and antipyretic properties. Topically, solutions containing 5% of phenazone have been used locally as ear drops in disorders such as otitis media because of its local anti-inflammatory and analgesic action. Glycerol softens wax.
Tetracaine hydrochloride is used as a local anaesthetic which acts by reversibly blocking the propagation and conduction of nerve impulses along nerve axons. Tetracaine stabilises the nerve membrane, preventing the increase in sodium permeability necessary for the production of an action potential.

5.2 Pharmacokinetic properties

Phenazone is readily absorbed from the gastro-intestinal tract and is distributed throughout the body fluids. Peak plasma concentrations are usually obtained in 1 to 2 hours. Less than 10% is bound to plasma proteins and it has a half-life of about 12 hours. Phenazone is metabolised in the liver, about 30% to 40% is metabolised to 4-hydroxyphenazone which is excreted in the urine as the glucuronide. Approximately 5% is excreted unchanged and approximately 6% is norphenazone in the urine.
Tetracaine is a weak base (pK_a 8.5), therefore, significant changes in the rate of ionised lipid soluble drug uptake may occur with changes in the acid base balance.
The primary site of metabolism for Tetracaine is the plasma.
Pseudocholinesterases in the plasma hydrolyse Tetracaine to 4-aminobenzoic acid. Unmetabolised drug is excreted in the urine.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

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.

6.5 Nature and contents of container

A bottle containing a clear, colorless to slightly yellow solution.
Approved package size: 10 ml

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 REGISTRATION HOLDER AND MANUFACTURER

Vitamed Pharmaceutical Industries Ltd., 6 Hatahana St., Binyamina, Israel.

8 DRUG REGISTRATION NUMBER AT THE NATIONAL DRUG REGISTRY OF THE MINISTRY OF HEALTH: 063-15-28051-00

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