

Package leaflet: information for the patient

OTOMIDONE 25 mg/ml + 28.8 mg/ml ear drops

Phenazone + procaine hydrochloride

Read this leaflet carefully before using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist told you to do.

- Keep this sheet. You may need to read it again.
- If you want more information or advice, ask your pharmacist.
- If you experience any side effects, including effects not listed in this sheet, contact your doctor or pharmacist. See paragraph 4.
- Talk to your doctor if you don't feel better or if you feel worse after 1-2 days.

Contents of this sheet:

1. What OTOMIDONE is and what it is used for
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1. What OTOMIDONE is and what it is used for

OTOMIDONE contains two active ingredients: phenazone, a painkiller, and procaine a local anesthetic.

This medicine is used to relieve pain in ear inflammation (otitis).

Talk to your doctor if you do not feel better or if you feel worse after 1-2 days.

2. What you need to know before using OTOMIDONE

Do not use OTOMIDONE

- if you are allergic to the active substances or any of the other components of this medicine (listed in paragraph 6);
- if you are particularly sensitive to the active ingredients (idiosyncrasy with procaine or phenazone);
- if you suffer from myasthenia gravis (which causes muscle weakness and tiredness);
- if your eardrum is damaged by an infection or trauma (perforation of the eardrum).

Warnings and precautions

Talk to your doctor or pharmacist before using OTOMIDONE if you think you have any injuries to the ear (injuries to the tympanic membrane). In case of ear injuries this medicine could cause effects that extend to the entire body (systemic).

Do not use for more than 10 days; after 1 – 2 days of treatment without appreciable results, consult the doctor. The use of products for topical (local) use can give rise to sensitization phenomena (excessive reaction of the body to foreign substances with which it has come into contact) or irritation.

In this case, stop treatment and consult your doctor.

Other medicines and OTOMIDONE

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine.

Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant, plan to have a pregnancy, or are breastfeeding breast milk, ask your doctor or pharmacist for advice before using this medicine.

If you are pregnant, use this medicine only if your doctor deems it necessary and under his advice and control.

Driving vehicles and using machinery

This medicine does not affect the ability to drive or use machines.

The OTOMIDONE container contains latex rubber

The container of this medicine contains latex rubber. May cause serious allergic reactions

3. How to use OTOMIDONE

Always use this medicine exactly as described in this leaflet or as per the instructions of the doctor or pharmacist. If you have any doubts, consult your doctor or pharmacist.

Do not exceed the recommended doses.

The recommended dose is 3 – 4 drops in each ear.

If you are elderly, limit yourself to using the lowest doses.

Application instructions

- clean your ear carefully with dry cotton;
- tilt your head to one side so that your ear (auricle) is in position horizontal;
- instill 3 – 4 drops of medicine;
- keep your head bent for at least 5 minutes
- plug your ear with a strip of hemmed gauze or a cotton ball.

The medicine can also be used lukewarm by heating the container in a bain-marie before use.

Duration of treatment

Repeat the application every hour until the pain disappears.

Subsequently, for 1 – 2 days, treat the ear every 2 – 3 hours.

Do not use the medicine for more than 10 days; after 1 – 2 days of treatment without appreciable results, consult your doctor.

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

4. Possible side effects

This medicine, like all medicines, can cause side effects although not all people manifest them.

Allergic reactions may occur in people sensitive to the active ingredients contained in this medicine.

In case of perforation of the eardrum, this medicine may cause side effects extend to the entire organism (systemic), such as:

- decrease in some blood cells (agranulocytosis);
- severe allergic reactions (anaphylactic manifestations).

Reporting of side effects

If you experience any side effects, including those not listed in this leaflet, report your doctor or pharmacist.

You can also report side effects directly via the national system reporting at <http://www.agenziafarmaco.gov.it/it/responsabili>.

By reporting side effects you can help provide more safety information of this medicine.

5. How to store OTOMIDONE

This medicine does not require any special storage conditions.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after 'Expiry'.

The expiry date refers to the last day of indicated month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how eliminate medicines you no longer use. This will help protect the environment.

6. Package contents and other information

What OTOMIDONE contains

- The active ingredients are phenazone, procaine hydrochloride. 1 ml of ear drops contains 25 mg of phenazone and 28.8 mg procaine hydrochloride.

- The other component is glycerol.

Description of the appearance of OTOMIDONE and contents of the pack

OTOMIDONE 25 mg/ml + 28.8 mg/ml ear drops is available in a 10 ml glass bottle.

Marketing authorization holder and manufacturer

SIT Pharmaceutical Laboratory S.r.l. - Via Cavour, 70 - 27035 Mede (PV)