

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

OTIPAX solution, ear drops Phenazone / Lidocaine hydrochloride

Read all of this leaflet carefully before you start 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 has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or your pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 10 days.

What is in this leaflet

1. What OTIPAX solution, ear drops is and what it is used for
2. What you need to know before you use OTIPAX solution, ear drops
3. How to use OTIPAX solution, ear drops
4. Possible side effects
5. How to store OTIPAX solution, ear drops
6. Contents of the pack and other information

1. WHAT OTIPAX solution, ear drops IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group:

local analgesic / anti-inflammatory for otological use. (S: Sensory organs).

Therapeutic indications:

OTIPAX is indicated for the local symptomatic treatment of certain painful conditions of the middle ear with intact tympanic membrane:

- Congestive acute otitis media
- Flu otitis so-called phlyctenular viral otitis
- Barotrauma otitis

You must talk to a doctor if you do not feel better or if you feel worse after 10 days.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE OTIPAX solution, ear drops

DO NOT USE OTIPAX solution, ear drops:

- If you are allergic to lidocaine or phenazone or any of the other ingredients of this medicine (listed in section 6).
- If you have a tympanic perforation of infectious or traumatic origin.

Warnings and precautions

Talk to your doctor or pharmacist before taking Otipax solution, ear drops.

- If there is an opening in the tympanic membrane (ear drum), this medicine may cause adverse effects in the middle ear.

Other medicines and OTIPAX solution, ear drops

Due to the local action of OTIPAX no drug interaction is expected.

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

Pregnancy and breastfeeding

This medicine can be used, in the normal way, during pregnancy or by nursing mothers if necessary.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Not relevant.

OTIPAX solution, ear drops contains glycerol.

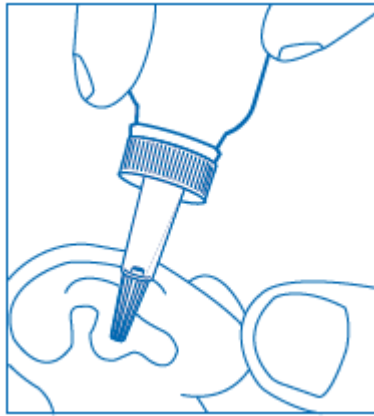
3. HOW TO USE OTIPAX solution, ear drops

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 4 drops 2-3 times a day in the auditory meatus.

Auricular route.

- Unscrew the cap of the bottle.
- Remove the dropper from its blister.
- Screw the dropper on the bottle.
- Uncap the dropper.
- Turn the bottle upside down while carefully pressing the dropper to release 1 drop.
- Press it further until you release 4 drops.
- Put the white cap on the dropper.



Do not exceed 10 days of treatment. If symptoms persist, consult your doctor.

If you forget to use OTIPAX solution, ear drops

Do not take a double dose to make up for a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- Rare (may affect up to 1 in 1,000 people): local reactions such as allergy, irritation or redness of the auditory meatus.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. ADR reporting – Website: www.medicinesauthority.gov.mt/adrportal

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

5. HOW TO STORE OTIPAX solution, ear drops

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 box and the bottle.

Do not use for more than 1 month after opening.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What OTIPAX solution, ear drops contains

The active substances are:

Phenazone.....	4g
Lidocaine hydrochloride.....	1g

For 100g solution, ear drops.

The other ingredients are:

Sodium thiosulphate, ethanol, glycerol, purified water.

What OTIPAX solution, ear drops looks like and contents of the pack

15ml-bottle containing a clear, colourless or very slightly amber liquid, with an alcohol odour.
One bottle of 16g of solution is packed with one dropper.

Marketing Authorization Holder and manufacturer

Marketing Authorization Holder

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94250 Gentilly
FRANCE

Manufacturer

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60000 Beauvais
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This leaflet was last revised in April 2017