

1. IDENTIFICATION OF MEDICINE**Name**

OTIPAX®, solution, ear drops.

Composition

Phenazone..... 4 g

Lidocaine hydrochloride..... 1 g

Excipients: sodium thiosulfate, ethanol, glycerol, purified water, for 100 g of solution.

Pharmaceutical form

Solution, ear drops in 16 g container.

Pharmaco-therapeutic groupLOCAL ANALGESIC / ANTI-INFLAMMATORY FOR OTOLOGICAL USE
(S : Sensory organs)**Name and address of**

the Marketing Authorization Holder

BIOCODEX7 avenue Gallieni
94250 Gentilly - France.**Name and address of the Manufacturer****BIOCODEX**1 avenue Blaise Pascal
60000 Beauvais - France.**2. WHEN SHOULD THIS MEDICINE BE USED?**

Local treatment of pain due to certain types of otitis with intact tympanic membrane (ear drum):

- congestive acute otitis media,
- so-called phlyctenular viral otitis,
- barotrauma otitis.

3. TAKE CARE!**When should this medicine not be used?**This medicine **MUST NOT BE USED** in the following situations:

- tympanic perforation (perforated ear drum),
- hypersensitivity to one of the components.

If in doubt, it is essential to seek the advice of your doctor or your pharmacist.**Special warnings**

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

AS A PRECAUTIONARY MEASURE, you should ask A DOCTOR to check that the drum is intact before using this medicine.

Precautions

Treatment should be for no longer than 10 days. If symptoms persist, CONSULT YOUR DOCTOR.

If in doubt, do not hesitate to seek the advice of your doctor or your pharmacist.**Drug interactions and other interactions**

In order to avoid possible interactions between several medicines, you should always inform your doctor or pharmacist of any other treatment that you may be taking.

Pregnancy - Lactation

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

As a matter of general principle, you should always seek the advice of your doctor or pharmacist before taking any medicine if you are pregnant or breast feeding.

Athletes

The attention of athletes is drawn to the fact that this medicine contains an active ingredient which may give a positive result in anti-doping tests.

Noticeable excipient

Glycerol.

4. HOW TO USE THIS MEDICINE**Dosage**

Warm the container between the hands before use so as to avoid the unpleasant feeling caused by the cold solution in the ear.


- **Dropper bottle:** instill 4 drops in the auditory meatus of the painful ear by applying gentle pressure to the soft part of the dropper, 2 or 3 times a day.**Method and route of administration**

Auricular route.

Frequency and times of administration

4 drops in the auditory meatus of the painful ear, 2 or 3 times a day.

Treatment durationTreatment should be for no longer than 10 days.
If symptoms persist, CONSULT YOUR DOCTOR.**How to use the dropper bottle:**

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- Unscrew the cap of the bottle,
 - Screw on the dropper on the bottle,
 - Remove the cap of the dropper,
 - Turn the bottle upside down then apply gently pressure to the dropper to obtain 1 drop,
 - Squeeze again until 4 drops are obtained,
 - Screw the white cap back on.

After opening the bottle, the solution must be used within 30 days.

5. UNDESIRABLE AND TROUBLESOME EFFECTS

In common with all active substances, this medicine may cause troublesome effects of varying degrees in certain individuals:

Risk of local reactions in the form of allergy, irritation or redness of the auditory meatus.

If in doubt, do not hesitate to tell your doctor or pharmacist and tell them about any other undesirable and troublesome effect not mentioned in this package insert information.**6. STORAGE****Do not exceed the expiry date shown on the outer packaging.****Special storage precautions:**

Store at a temperature below 30°C.

7. DATE OF REVISION OF PACKAGE INSERT INFORMATION

November 2005.