SUMMARY OF PRODUCTCHARACTERISTICS

1. NAME OF MEDICINAL PRODUCT

OTIPAX®

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition: 1g solution contain:
Active substances:
Phenazon.....40mg
Lidocainehydrochloride.....10 mg

Excipients: sodium thiosulfate, ethanol, glycerol, purified water.

Excipient with known effect: glycerol.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ear drops solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Local symptomatic treatment of certain painful conditions of the middle ear with intact tympanic membrane:
- acute otitis media,
- otitis, as a complication after flue
- barotrauma otitis.

4.2. Dosage and method of administration

Auricular route.
In order to avoid unpleasant contact of the cold solution with the ear, warm the container between the hands before use.
- Dropper bottle: instil 4 drops in the auditory meatus by applying gentle pressure to the soft part of the dropper, 2 or 3 times a day in the painful ear.

4.3. Contraindications

- tympanic perforation of infectious or traumatic origin (see section 4.4),
- hypersensitivity to the active ingredient or to any of the components listed in section 6.1.

4.4. Special warnings and precautions for use

Special Warnings
As a precautionary measure, ENSURE THAT THE TYMPANIC MEMBRANE IS INTACT BEFORE ANY ADMINISTRATION.
If there is tympanic breach, intra-auricular administration may bring the product into contact with the structures of the middle ear, with adverse effects upon them.
This medicine contains an active ingredient which may give a positive result in the anti-doping tests.

Precautions for use
Limit treatment duration to 10 days. Management must be reviewed after that time.

4.5. Interactions with other medicines and other forms of interaction

The data available to date do not suggest the possibility of clinically significant interactions.

4.6. Fertility, pregnancy and lactation

In the absence of any tympanic breach, systemic penetration is unlikely.
As a result, under normal conditions of use, this medicine can, if necessary, be used during pregnancy and lactation.

4.7. Effects on ability to drive and use machines

No effects on ability to drive and use machines.

4.8. Undesirable effects

The side effects are rare (may affect up to 1 in 1000 people): local reactions such as allergy, irritation or redness ofthe auditory meatus.

4.9. Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: **LOCAL ANALGESIC/ANTI-INFLAMMATORY FOR OTOLOGICAL USE**
S: Sensory organs, ATC code: S02DA30
Phenazone: pyrazolone derivative with analgesic and anti-inflammatory properties.
Lidocaine: local anesthetic of the amide group.

5.2. Pharmacokinetic properties

No systemic absorption unless in the presence of tympanic breach.

5.3. Preclinical safety data

None.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sodium thiosulphate, ethanol, glycerol and purified water.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years.
Use during 1 month after first opening.

6.4. Special precautions for storage

Store away from light at a temperature below 25°C.

6.5. Nature and contents of container

Bottle (yellow glass type III) of 15 ml (containing 16 g of solution) closed by a stopper (LDPE) with a seal (LDPE) and a dropper (PE/vinyl acetate) and a stopper (LDPE).

6.6. Special precautions for disposal

No special requirements.

7. MANUFACTURER AND MARKETING AUTHORIZATION HOLDER

Manufacturer address
BIOCODEX
1 avenue Blaise Pascal
60000 BEAUVAIS
FRANCE

Marketing Authorization Holder
BIOCODEX
7 AVENUE GALLIENI
94250 GENTILLY
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

N 12093

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE MEDICINAL PRODUCT

22/07/2002

10. DATE OF REVISION OF THE TEXT

22/01/2018

CONDITIONS OF PRESCRIPTION AND DELIVERY

Without medical prescription.