

*Dear Patient*

*Please read this leaflet carefully. It contains important information that you should know about when using this medical device.*

*If you have any further questions, ask your doctor or pharmacist.*

**Directions for use**

**For softening hardened ear wax (cerumen)**

Otitex 10 ml solution for instilling into the auditory canal.

Composition:

Glycerol, ethanol, docusate sodium, buffering agents (monosodium phosphate, sodium hydroxide), purified water.

Marketing authorisation holder:

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**Therapeutic indications**

For softening hardened ear wax. Dissolving cerumen prior to a medical ear examination and prior to treatment of the ear with topical drugs. Otitex is well suited for keeping the auditory canal clean in patients wearing hearing aids.

**Contraindications**

Otitex may not be used in the case of

- damaged (perforated) eardrum
- hypersensitivity reactions to any of the ingredients
- hypersensitivity of the auditory canal
- injuries or inflammations of the auditory canal
- ear infections

**Side effects**

Otitex may cause painful symptoms depending on the condition of the auditory canal, for example if there are injuries or inflammatory disorders in the auditory canal. In this event, it is advisable to rinse out the auditory canal thoroughly with water at body temperature and not to continue using Otitex.

**Interaction with other medical devices and other forms of interaction**

Otitex may not be used together with other medicines for the topical treatment of the auditory canal.

**Dosage instructions**

The following dosages may be regarded as a general guideline:

Single dose: instil 10 –15 drops into the auditory canal.

**Method of application**

Otitex should be used at body temperature. The patient should lie on his side and Otitex should be instilled into the auditory canal. One drop is released at a time by lightly squeezing the wall of the bottle. The ear should then be plugged with cotton wool to allow Otitex to act on the cerumen (ear wax). The softened ear wax should be rinsed out thoroughly after 5 to 10 minutes using water at body temperature.

**Duration of application**

Application should be repeated in the case of cerumen that has become extremely hard. Otitex should be used regularly according to the doctor's recommendation in the event of overproduction of cerumen.

**1** The security seal on the bottle can be opened by turning it in an anticlockwise direction.

**2** After the bottle has been opened, the drops are instilled into the auditory canal at the dose directed, by exerting pressure on the plastic bottle.

**3** After use, the bottle should be closed and stored at normal room temperature.

**Special warning**

- Keep medical devices away from children.
- Store Otitex out of the reach of children.
- Do not allow Otitex to come into contact with the eyes; rinse out eyes immediately with copious amounts of water.

**Shelf life**

- Do not keep for longer than 6 months after opening.
- Otitex should not be used after the expiry date on the pack.

**Special notes**

The use of pointed objects to clean the auditory canal mechanically is not advisable because of the risk of injury. Agents or aids that push the cerumen into the rear section of the auditory canal are not suitable for cleaning purposes either.

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