

Text to appear on the Patient Information Leaflet

AUDAX Ear drops

Choline salicylate solution 43.22% w/v
and Glycerol 12.62% w/v

PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before using Audax Ear Drops.

- Keep this leaflet, you may wish to read it again.
- Ask your pharmacist if you need more information or advice.

In this leaflet:

1. What Audax Ear Drops are and what they are used for?
2. Before you use Audax Ear Drops
3. How to use Audax Ear Drops
4. Possible side effects
5. How to store Audax Ear Drops
6. Further information

1. What Audax Ear Drops are and what they are used for?

These drops should be used for the relief of **ear pain** in acute and chronic internal and external earache.

If you have ear pain you should always speak to your doctor or pharmacist.

They are also used for the **softening of ear wax** as an aid to ear wax removal.

2. Before you use Audax Ear Drops**Do not use Audax Ear Drops**

- If you are allergic to active ingredient choline salicylate or glycerol or any of the other ingredients in this product. See 'What these drops contain' for the full list of ingredients.
- If you have a perforated or bleeding ear drum.
- If you are pregnant or think you may be pregnant or are planning to have a baby
- On children under 1 year of age, unless advised by your doctor.

Take special care...

- Make sure Audax Ear Drops are suitable for you to use - ask your doctor or pharmacist.

Pregnancy and breastfeeding....

If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine. Speak to your doctor...

- If symptoms persist beyond 4 days or get worse, talk to your doctor or pharmacist.
 - Audax ear drops contains propylene glycol this may cause skin irritation
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3. How to use Audax Ear Drops

Adults, the elderly and infants over 1 year old:

For Pain Relief

- With the head tilted to one side, completely fill the external ear canal with Audax Ear Drops using the dropper provided.
- Following this the ear should be plugged with cotton wool soaked with the ear drops.
- A wick may then be inserted, if preferred, using the ear drops to keep it moist.
- Audax Ear Drops should be instilled every three to four hours.

For Softening of Ear Wax

- Apply as described for pain relief, twice daily, for four days.

If you accidentally swallow the drops...

These drops are for use in the ear only. Do not put them in your mouth or swallow them. If you do accidentally swallow them, speak to your doctor or pharmacist.

Swallowing the drops is of particular concern in small infants, where signs of overdose may include dizziness, ringing in the ears, sweating, vomiting, confusion and increased rate of breathing.

4. Possible side effects

Skin irritation and allergic reactions like skin rash, swelling of the skin, irritation & inflammation inside the nose, difficulty in breathing and asthma have been reported in patients sensitive to NSAIDs. If you feel you are reacting badly to this medicine in any way, then stop using the drops and speak to your doctor or pharmacist.

Audax Ear Drops

- Keep out of the reach and sight of children.
- Do not store above 25°C.
- Do not use after the expiry date shown on the label and carton.
- If you find that you still have this medicine after its expiry date, return it to your local pharmacist who will dispose of it properly.

6. Further information

What Audax Ear Drops contain

Audax Ear Drops contain 43.22% by volume of the active ingredient choline salicylate solution (equivalent to choline salicylate 20% by volume) and 12.62% by volume of the active ingredient glycerol. Choline salicylate possesses analgesic, anti-inflammatory and anti-pyretic properties and glycerol softens ear wax due to its water retaining and emollient properties.

They also contain ethylene oxide polyoxypropylene glycol, chlorbutol (hemihydrate), hydrochloric acid and propylene glycol.

The drops are a clear, odourless, very pale yellow liquid contained in cartoned amber glass bottles incorporating a screw cap and integral dropper of 10ml.

Marketing Authorisation Holder: **LanesHealth (Ireland) Ltd, Suite 7, The Courtyard, Carmanhall Road, Sandyford, Dublin, D18 NW62 Ireland.**

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