

EAR RELIEF

EAR DROPS

Contents:

1. What **CI-ear Ear Relief** is and what it is used for?
2. Important information before use.
3. How to use **CI-ear Ear Relief**.
4. Possible side effects.
5. How to store **CI-ear Ear Relief**?
6. Other information.

Ingredients: 0,5% solution of lidocaine hydrochloride in glycerol (anhydrous).

1. What **CI-ear Ear Relief** is and what it is used for?

CI-ear Ear Relief ear drops is a medical device, the action of which is based on the osmotic properties of glycerol. The main component of **CI-ear Ear Relief** is glycerol. Glycerol has two basic characteristics relevant to its use in ear drops: i) the oily consistency of glycerol, which causes it to adhere gently to the skin at the application site and is responsible for its protective properties and ii) hygroscopicity of glycerol, which in turn causes glycerol administered topically to remove water from swollen tissues (osmotic effect), resulting in swelling reduction, and thus the alleviation of pain. Lidocaine is used as a surface anaesthetic auxiliary agent, which intensifies the action and additionally soothes ear pain.

Glycerol in **CI-ear Ear Relief** medical device softens wax, helps in its removal and thanks to its water-binding properties removes excess of fluid from the tissues of the auditory canal (osmotic effect), thus leading to the elimination of ailments occurring in inflammatory conditions of the ear such as ear pain and swelling. Glycerol has a causal effect. Lidocaine is used as an auxiliary agent in **CI-ear Ear Relief** as a surface anaesthetic agent, intensifies the activity of glycerol and additionally soothes ear pain.

CI-ear Ear Relief has a supportive effect on:

- inflammatory conditions characterised by swelling, pain and itching of the outer ear canal.
- ailments accompanied by pain caused by regular exposure to water and moisture, e.g. a swimming pool
- ailments accompanied by pain caused by prolonged wearing of headphones or wax, which clogs the external auditory canal
- ailments accompanied by pain caused by frequent use of detergents, which destroy the natural membrane protecting the external ear canal, e.g. shampoos, soaps, gels.

CI-ear Ear Relief can be used in children from 5 years of age.

2) Important information before use.

Contraindications and warnings

Do not use **CI-ear Ear Relief**:

- if the packaging has been damaged;
- if the ear drum is damaged (e.g. chronic otitis media);
- **CI-ear Ear Relief** should only be used after a thorough otoscopic examination by a doctor;
- an allergy to any of the components of the product has been previously detected;
- the expiry date printed on the packaging has expired;
- the patient is immediately after surgery or surgical treatment in the ear;
- in children under 5 years of age;
- in case of prolonged pain or swelling caused by inflammatory condition with bacterial or fungal basis, these ailments require contact with a doctor;
- in case of ear discharge - leakage from the ear;
- **CI-ear Ear Relief** should not be applied to the ear with the hearing aid fitted, **CI-ear Ear Relief** should be applied one hour before the hearing aid is ingested into the outer ear canal;
- Although there is no evidence that **CI-ear Ear Relief** drops have a negative effect when used during pregnancy and breast-feeding, the use of **CI-ear Ear Relief** drops should be consulted with a doctor who should assess whether the expected benefits of **CI-ear Ear Relief** exceed the potential risk.
- If symptoms intensify or there is no improvement after three days of using **CI-ear Ear Relief** ear drops or if you have a fever, contact your doctor. Prolonged pain or swelling may signal a bacterial or fungal infection that may require further and more appropriate treatment;
- **For external use only**
- **Avoid contact with eyes, mouth and throat and nose mucous membranes.**
- **CI-ear Ear Relief** is intended for temporary relief of ear pain, no longer than 3 days and should not be used chronically.

Use with other medicinal products/medical devices

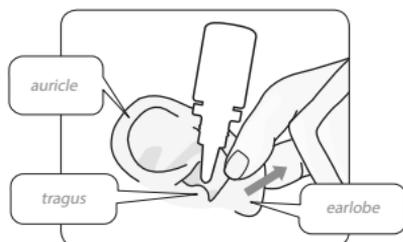
Interactions with other products have not been studied. However it is known that anti-arrhythmic drugs exacerbate the side effects of lidocaine; parallel use may lead to serious side effects. Cimetidine, β -blockers, norepinephrine, inhaled anaesthetics inhibit lidocaine metabolism through decreased hepatic flow, leading to increased

serum drug levels.

Barbiturates, rifampicin, and phenytoin accelerate the metabolism of lidocaine through the activation of liver microsomal enzymes. Lidocaine enhances the effect of transversely ribbed muscle relaxants. The manufacturer does not recommend the use of other medicinal products / medical devices in the form of drops or sprays during the use of **CI-ear Ear Relief**. The use of other medicinal products / medical devices in the form of drops or a spray should be consulted with a doctor or a pharmacist. Before applying **CI-ear Ear Relief** drops tell your doctor or pharmacist about other products that are used in the ear and all medicines recently taken, including those that are over the counter. After using drops, it is not recommended to use any other medicinal products, medical devices or ear drops for at least 30 minutes.

3) How to use **CI-ear Ear Relief**.

1. Wash your hands and then unscrew the cap from the bottle.
2. Tilt your head or lie down on your side so that the treated ear faces upwards.
3. Gently pull the earlobe (lower part of the ear canal) from the neck.
4. Turn the unscrewed **CI-ear Ear Relief** bottle upside down and by pressing it on both sides measure 1-2 drops of the product into the ear.
5. Hold the head tilted for a few minutes so that the drops can flow into the ear canal.
6. Wipe off excess liquid with a clean tissue.
7. In addition, it is recommended that the outer ear canal is clogged with cotton wool after application.
8. Replace the cap.



Dosage

Adults and children over 12 years of age: 2 drops to each ear up to three times a day. If there is no improvement after 3 days or if you feel worse, consult your doctor.

Children over 5 years of age; 2 drops to each ear up to three times a day. **Use only under the supervision of an adult or a doctor.** If there is no improvement after 3 days or if you feel worse, consult your doctor.

In case of use in children it is necessary to protect the ear with cotton wool.

CI-ear Ear Relief can not be used in children below 6 months of age.
For external use only The success of treatment should be monitored by a doctor.

CI-ear Ear Relief contains 7g of solution

4) Possible side effects.

CI-ear Ear Relief is well tolerated and no adverse effects are known after its use. In case of allergy or other undesired effects, inform your doctor or pharmacist and stop using the drops. **CI-ear Ear Relief** should only be used in accordance with the instructions for use.

5. How to store **CI-ear Ear Relief**?

CI-ear Ear Relief should be stored:

- in a dry place, at a temperature of 15°C to 25°C in an upright position;
 - protect from frost and do not store in the refrigerator;
 - protect against direct sunlight;
 - in a place invisible and inaccessible to children.
- after the first opening of the **CI-ear Ear Relief** package can be used for 4 weeks.

Write the date of the first application of the drops on the bottle (designated place).

After use, dispose of the packaging in accordance with local regulations.

6) Other Information

CI-ear Ear Relief is a class III medical device.  1434

Packing:

Multi-dose bottle contains 7 g of solution.

Manufacturer: EmurgoPharm Sp. zo.o. Sp.K.
ul. Piłsudskiego 11, 05-510 Konstancin Jeziorna, Poland

Explanation of the symbols used

 15°C to 25°C
limitation of the permitted storage temperature

 refer to the instructions for use

 manufacturer

 warning

 CE conformity marking

 protect from sunlight

 do not use if the packaging is damaged

 series number

 best before