

Otex[®]

EAR DROPS

READ THESE INSTRUCTIONS CAREFULLY BEFORE USE

What you should know about Otex[®] Ear Drops (urea hydrogen peroxide)

About your treatment

The name of your treatment is Otex. It contains 5% urea hydrogen peroxide as the active ingredient. It also contains the inactive ingredients 8-hydroxyquinoline and glycerol. Otex is a clear, straw coloured viscous solution. This bottle contains 8ml of Otex.

The active ingredient works by softening the hardened ear wax and breaking it down into small flakes.

(OTEX IS MADE FOR THE PRODUCT LICENCE HOLDER, DIOMED DEVELOPMENTS LTD, HITCHIN, HERTS, SG4 7QR, UK AT DDD LTD, WATFORD, HERTS, WD18 7JJ, UK)

Your doctor or pharmacist has recommended or supplied Otex to help remove excessive, hardened wax in your ear.

Ear wax is produced by tiny glands in the skin which line the ear canal. This process is important in maintaining cleanliness and helping to protect against infection. In most people, the thin layer of wax breaks down naturally into tiny flakes, which are then lost from the ear almost unnoticed.

Some people produce large quantities of ear wax, however, which can build up and cause a blockage in the ear. As the blockage continues to grow, the first symptom is usually a feeling of discomfort and fullness in the ear. This can become painful and cause dizziness and some loss of hearing if left untreated. At this stage, the temptation to try to remove the wax using a cotton

bud, or similar device, must be resisted. Excess ear wax is quite common, but is usually simple to treat, using wax-removing ear drops. Otex Ear Drops work by softening and breaking down the wax into small pieces, which can then be released from the ear more easily. In many cases, this should avoid the need for syringing.

When NOT to use Otex

- DO NOT USE OTEX IF YOUR EAR DRUM IS (OR HAS BEEN) DAMAGED.
- DO NOT use Otex if you are sensitive to any of its ingredients (as listed on the left).
- DO NOT use Otex if you suffer from dizziness, or if there is any other ear disorder (such as pain, discharge, inflammation, infection or tinnitus).
- DO NOT use Otex after ill-advised mechanical efforts to dislodge wax using fingernails, cotton buds or similar implements, as such efforts can cause the ear's delicate inner lining to become damaged, inflamed or infected, whereupon the use of ear drops can be painful. For similar reasons, it is inadvisable to use Otex for 2-3 days after syringing.
- DO NOT use Otex if anything else has been used in the ear.
- DO NOT use Otex if you have a history of ear problems, unless under close medical supervision.
- If in any doubt whether to use Otex, consult a doctor before use.

For your safety

Keep Otex away from the eyes. In case of accidental contact, wash eyes immediately with water; keep rinsing for 10 to 15 minutes, holding the eyelids well apart and avoid getting the liquid into the other eye. Consult a doctor if irritation persists.

How to use Otex

Otex is for use only in the ears.

The same instructions apply to adults, children and the elderly:

- Turn the cap anti-clockwise to break the seal. Tilt head, and gently squeeze up to 5 drops into the ear. Leave for a few minutes and then wipe away any surplus with a tissue. Repeat if necessary in the other ear. Wash hands after use.
- Repeat once or twice daily, if necessary, whilst symptoms clear. Treatment usually takes 3 to 4 days, after which an improvement in hearing should be noticed, with a reduction in the discomfort felt in the ear. Do not “plug” the ears with loose cotton wool during the treatment period. Always replace the cap after use and return the bottle to the carton.
- In some cases, excessive wax may persist for more than 3 to 4 days, despite softening, or may be so hardened that ear drops alone are not sufficient to clear the ear canal. This may result in some temporary loss of hearing. In these cases your doctor should be consulted for further advice.

During your treatment

Make sure that the section overleaf **When NOT to use Otex** does not apply to you.

During use, a temporary bubbling sensation in the ear may sometimes occur.

The build up of excess ear wax may be painful, especially if packed against the ear drum, and may result in some loss of hearing, dizziness or tinnitus. These effects may be aggravated by the wax expanding and creating pressure in the ear canal. In a similar way, this can also occur following, for example, absorption of water by the wax after swimming or showering, or from the use of ear drops, such as Otex.

Very rarely, unpleasant taste has been reported. If you encounter any of these problems, or if your symptoms persist or worsen, discontinue treatment and consult a doctor.

As hardened ear wax softens, before it is removed or dispersed, it is inclined to swell in the ear canal. The use of ear drops may therefore be associated with a feeling of fullness in the ear and some temporary distortion of hearing, which may occasionally give rise to slight dizziness, impaired balance or tinnitus. If the ear canal has been abraded or otherwise irritated, as may occur if the ear has been wiggled to unblock it, or if wax removal has been attempted by using fingers, cotton buds or other implements, the use of Otex may be inadvisable in case it coincides with inflammation or infection, which can cause discomfort or pain. Should these symptoms occur, seek advice and appropriate treatment from your doctor.

You should also seek medical advice if you experience any undesirable effects when using Otex, or if the preparation is accidentally swallowed.

How to handle and store Otex

This product should not be used after the expiry date shown on the bottle. Store Otex upright, where children cannot see or reach it. Do not store above 25°C.

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Distributed by:

DDD Limited, 94 Rickmansworth Road, Watford,
Herts, WD18 7JJ, UK.

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