

**Please read all of this leaflet carefully before you start using this product.**

Keep this leaflet. You may need to read it again. Ask your doctor, nurse or pharmacist if you need more information or advice. You must contact a doctor if your symptoms worsen or do not improve within a reasonable period.

In this leaflet:

1. What Otex Express Combi Pack is and what it is used for
2. Before you use Otex Express Combi Pack
3. How to use Otex Express Combi Pack
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1. WHAT OTEX EXPRESS COMBI PACK IS AND WHAT IT IS USED FOR

- Otex Express Combi Pack contains a bottle of Otex Express ear drops and a bulb syringe, which are used to help remove hardened wax from the ear canal.
- The ear drops work by breaking down the ear wax into small pieces, and the bulb syringe may be used after treatment to rinse out remaining ear wax or ear drops.
- The therapeutic ingredient in the ear drops is urea hydrogen peroxide. It works by breaking down the ear wax into smaller pieces.
- Excessive, hardened ear wax is quite common. It causes problems when it builds up and blocks the ear canal. 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.
- Otex Express Combi Pack makes removal of ear wax easier, and in many cases avoids the need for ear syringing by a doctor or nurse.
- Otex Express Combi Pack is suitable for use by **adults, the elderly and children over 12 years old**.

2. BEFORE YOU USE OTEX EXPRESS COMBI PACK**Do not use Otex Express ear drops or the bulb syringe:**

- If you are **allergic (hypersensitive)** to any of the ingredients of Otex Express ear drops listed in Section 6.
- If you have a history of ear problems, unless used under the close supervision of your doctor, nurse or pharmacist.
- If you are also putting anything else in the ear (such as other ear drops or a hearing aid).
- If your ear drum is (or has been) damaged.
- If you suffer from dizziness.
- If there is anything else wrong with your ear - such as pain, swelling, discharge, infection or tinnitus (ringing sounds in the ear).
- If you have tried to remove the ear wax using fingernails, cotton buds or other implements. (This is because you might have damaged the delicate inner lining of the ear, leading to swelling or infection.) This could make it painful to use the ear drops or bulb syringe.
- If you have had your ear syringed in the last 2 to 3 days – this could also make it painful to use the ear drops or bulb syringe.

Take special care when using this product:

- A doctor should be consulted before using the ear drops in children under the age of 5 years to confirm that a build up of ear wax is present.
- Do not use the bulb syringe on children under 12 years old unless recommended to do so by a doctor. This is because ear irrigation should generally be avoided in children under 12 years old.
- If you are in any doubt whether this product is suitable for you, or how to use it, talk to your doctor, nurse or pharmacist before use.

If Otex Express gets into the eyes:

- Take care to avoid getting Otex Express ear drops in your eyes.
- If this happens, rinse the eye immediately with water for 10 to 15 minutes, holding the eyelids apart and avoiding getting the rinse liquid in the other eye.
- Tell your doctor or pharmacist if irritation persists.

Using other medical products and hearing aids:

- It is important not to use Otex Express ear drops or the bulb syringe if you are putting anything else in the ear (such as other ear drops, ear medicines or a hearing aid).
- Use of Otex Express ear drops or the bulb syringe is not known to affect, or to be affected by, any other kinds of medicines that you may be using.

Pregnancy and breast-feeding:

Otex Express ear drops and the bulb syringe can be used during pregnancy and while breast-feeding. The ingredients in the ear drops have been in widespread use in this and similar preparations for many years, without reports of problems. However, safety trials have not been conducted.

Driving and using machinery:

Using this product is not known to affect your ability to drive or use machinery. However, the build up of ear wax can cause dizziness, and this may be made worse by using the ear drops or bulb syringe (see Section 4). If you are affected, do not drive or use machinery.

3. HOW TO USE OTEX EXPRESS COMBI PACK

Only use in the ears.

For adults, the elderly and children over 12 years old:

Step 1: With the **ear drops, repeat** the following **once or twice daily, normally for 3 to 4 days**, until you notice an improvement in your hearing and less discomfort:

1. Turn the cap anti-clockwise. (This will break the seal when you use the ear drops for the first time).
2. Remove the cap to reveal the applicator nozzle. Keep the cap out of the reach of small children as it may pose a choking hazard.
3. Tilt your head and gently squeeze up to 5 drops into the ear.
4. Keep your head tilted sideways for a few minutes so that the drops stay in the ear.
5. Then wipe away any surplus with a tissue.

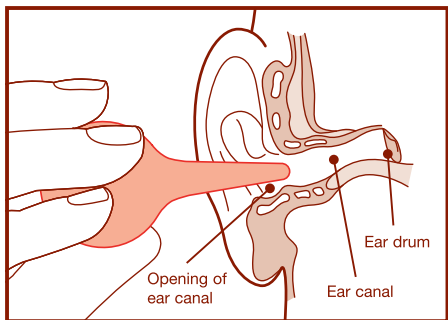
6. Repeat in the other ear, if necessary.

- Wash hands after use.
- Always replace the cap after use and return the bottle to the carton.
- **Do not** “plug” the ears with loose cotton wool.

In many cases this treatment is sufficient to expel the ear wax naturally.

Step 2: Any ear wax or drops remaining in the ear after using the drops for 3 to 4 days may be rinsed out using the **bulb syringe**, as follows:

1. Prior to use and after every subsequent use, wash the syringe inside and out with soapy water.
2. Fill a wash basin with warm (not hot) water.
3. Fill the bulb syringe with this water by squeezing the bulb and then allowing it to re-inflate with the nozzle below the surface of the water.
4. Holding your head tilted sideways over the wash basin
 - Gently position the nozzle of the bulb syringe into the opening of the ear canal but no further (see diagram).



- Rinse the ear canal by **gently** squeezing the bulb, letting the rinse water fall into the wash basin.
 - To avoid undesirable suction and pressure effects remove the bulb syringe in its squeezed position carefully out of the ear canal.
5. If necessary repeat steps 2 and 3 a couple of times to clean the ear canal (but do not persist if it feels uncomfortable).
 6. Tilt the head to allow excess water to drain from the ear, wiping away any surplus water with a tissue.
 7. Repeat for the other ear if required, except in cases where temporary diminished hearing or dizziness has occurred, in which case it may be advisable to allow an interval of at least one day before syringing the other ear.
- **Do not** push the nozzle of the bulb syringe deep into the ear canal, or squirt the contents into the ear with undue pressure, because this may cause serious damage to the ear drum and impaired hearing.
 - **Do not** allow the nozzle of the bulb syringe to block the flow of water leaving the ear, because this may cause serious damage to the ear drum and impaired hearing.
 - **Do not** use syringe to instil ear drops.

Note that in some cases, particularly hard or excessive ear wax may persist for more than 3 to 4 days, despite softening and use of the bulb syringe. This may cause some temporary loss of hearing. In these cases you should consult your doctor, nurse or pharmacist for further advice.

If you use more Otex Express ear drops than you should:

Do not worry if you use too much Otex Express ear drops. Simply wipe away any surplus running from the ear with a tissue.

If you forget to use Otex Express ear drops:

Do not worry if you occasionally forget to use Otex Express ear drops. When you remember, just carry on using this product once or twice daily as usual. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all ear treatments, this product can cause side effects, although not everybody gets them.

- A temporary mild bubbling sensation in the ear can occur after use of the ear drops (due to the release of oxygen as the drops break down the ear wax).
- Use of the ear drops or irrigation of the ear with the bulb syringe can make the symptoms of excessive ear wax worse, including some discomfort, irritation or pain, temporary loss of hearing, dizziness and tinnitus (ringing sound in the ear), as commonly happens after swimming.
- Very rarely, an unpleasant taste has been reported when using the ear drops. If this happens, stop using the ear drops immediately, do not use the bulb syringe, and seek advice from your doctor.

Stop using this product and tell your doctor or pharmacist if:

- Symptoms persist or,
- If any of the side effects get serious or you notice any other side effects not mentioned in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the procedure pack producer (PPP) (see Section 6 below), or via: United Kingdom: Devices Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard. By reporting side effects you can provide more information on the safety of this product.

5. HOW TO STORE OTEX EXPRESS COMBI PACK

- Keep out of the sight and reach of children.
- Do not use the ear drops or the bulb syringe after the use by date shown on the bottle label and the carton. The use by date refers to the last day of that month.
- Once opened, do not keep the bottle for longer than 4 weeks.
- Store below 25°C in a cool place and keep out of sunlight.
- Always replace the bottle cap tightly after use.
- Store the bottle upright in the outer carton to avoid spillage, and return the bulb syringe to the carton after cleaning with mild detergent, then rinsing.
- Dispose of product in normal household waste.

6. FURTHER INFORMATION ABOUT OTEX EXPRESS COMBI PACK

Otex Express ear drops contain urea hydrogen peroxide 5%, 8-hydroxyquinoline and glycerol.

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What the contents of Otex Express Combi Pack look like:

- The white plastic bottle contains 10ml of Otex Express ear drops. The bottle is fitted with a dropper and screwcap.
- The ear drops are a clear, straw coloured solution.
- The pack also contains a red-brown coloured bulb syringe

PPP Diomed Developments Ltd, Tatmore Place, Gosmore, Hitchin, Herts, SG4 7QR, UK, owners of 'Otex' Registered Trademark.

This leaflet was last revised in April 2024.

 Consult Instructions for Use

 Batch Code

 Use-by Date

PPP Procedure Pack Producer