

PACKAGE LEAFLET

Information for the user



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, nurse or pharmacist if your symptoms worsen or do not improve within a reasonable period.

In this leaflet:

1. What the ear drops are used for
2. Before you use the ear drops
3. How to use the ear drops
4. Possible side effects
5. How to store the ear drops
6. Further information

1. WHAT THE EAR DROPS ARE USED FOR

- Otex Sodium Bicarbonate Ear Drops are used to soften and help remove hardened wax from the ear canal.
- 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.
- The ear drops act physically to gently soften ear wax. Normally this is enough to encourage the ear wax to dislodge from the ear canal and fall out naturally (e.g. at night when you are laying down). If the drops alone are insufficient, their softening action makes it easier for a doctor or nurse to remove the ear wax using techniques such as ear syringing (irrigation).
- The ear drops are suitable for use by **adults, the elderly and children**. A doctor should be consulted before use in children under the age of 5 years to confirm that a build-up of ear wax is present.

2. BEFORE YOU USE THE EAR DROPS

Do not use Otex Sodium Bicarbonate Ear Drops:

- If you are **allergic (hypersensitive)** to any of the ingredients listed in Section 6.
- If you have a history of ear problems, unless you are using it 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 you have had your ear syringed in the last 2 to 3 days.
- 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.
- If the dropper is broken or damaged.

Take special care when using this product:

- If you are in any doubt whether this product is suitable for you, talk to your doctor, nurse or pharmacist before use.

If the ear drops get into the eyes:

- Take care to avoid the ear drops getting 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, nurse or pharmacist if irritation persists.

Using other medical products and hearing aids:

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

Pregnancy and breast-feeding:

The ear drops can be used during pregnancy and while breast-feeding. The ingredients have been in widespread use 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 (see Section 4). If you are affected, do not drive or use machinery.

Continued overleaf...

3. HOW TO USE THE EAR DROPS

Only use in the ears.

For adults, the elderly and children. Children under 5 years of age should be seen by a doctor before use to confirm a build-up of ear wax.

The drops are intended to soften and clear the ear wax or to aid subsequent ear syringing (irrigation) if necessary. Any softening and expansion of the wax volume may cause some temporary loss of hearing. If the drops alone are insufficient, it will be necessary for you to see a doctor or nurse for further advice.

Repeat the following twice daily for up to 5 days:

- Turn the cap anti-clockwise. (This will break the seal when you use the drops for the first time.)
- Remove the cap and discard it carefully because it may pose a choking hazard for small children. Following the first use, the dropper acts as a replacement for the original cap.
- Remove the dropper from the separate sachet, insert it into the bottle and fill with the ear drops.
- Tilt your head and use the dropper to gently release 3 to 4 drops into the ear.
- Avoid touching the ear with the dropper.
- Keep your head tilted for a few minutes so that the drops stay in the ear.
- Then use a tissue to wipe away any surplus product that runs from the ear.
- Repeat in the other ear, if necessary.
- Wash hands after use.
- **Do not** “plug” the ears with cotton wool.
- Always replace the screw cap of the dropper tightly after use and return the bottle to the carton.

If you use more of the ear drops than you should

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

If you forget to use the ear drops

Do not worry if you occasionally forget to use the drops. When you remember, just carry on using twice daily as usual.

If you have any further questions on the use of this product, ask your doctor, nurse or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all ear drops, Otex Sodium Bicarbonate Ear Drops can cause side effects, although not everybody gets them.

- The ear drops can make the symptoms of excessive ear wax worse, including some discomfort, irritation or pain, loss of hearing, dizziness and tinnitus (ringing sound in the ear).

- Very rarely, an unpleasant taste has been reported when using ear drops. Stop using the ear drops immediately if this happens and tell your doctor.

Stop using this product and tell your doctor, nurse 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.

5. HOW TO STORE THE EAR DROPS

- Keep out of the sight and reach of children.
- Do not use after the use by date shown on the bottle 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.
- Do not store above 25°C.
- Always replace the screw cap of the dropper tightly after use.
- Store the bottle in the carton with this leaflet.


6. FURTHER INFORMATION ABOUT THE EAR DROPS

Otex Sodium Bicarbonate Ear Drops contain sodium bicarbonate, glycerol, dichlorobenzyl alcohol and purified water.

What the product looks like and contents of the pack

- The amber glass bottle contains 10 ml of Otex Sodium Bicarbonate Ear Drops. It is supplied with this leaflet and a separate dropper which also acts as a replacement screw cap.
- The ear drops are a colourless liquid.

Otex Sodium Bicarbonate Ear Drops are distributed by

DDD Ltd, Watford, Herts, WD18 7JJ for  Diomed Developments Ltd, Hitchin, Herts, SG4 7QR, UK, owners of 'Otex' Registered Trademark.

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Consult Instructions for Use



Batch Code



Use-by Date



Manufacturer