

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

In this leaflet:

1. What Otex Olive Oil is and what it is used for
2. Before you use Otex Olive Oil
3. How to use Otex Olive Oil
4. Possible side effects
5. How to store Otex Olive Oil
6. Further information

1. WHAT OTEX OLIVE OIL IS AND WHAT IT IS USED FOR

- Otex Olive Oil ear drops are used to help soften and 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.

- Otex Olive Oil makes removal of ear wax easier, and may avoid the need for ear syringing.
- Otex Olive Oil is suitable for use by **adults, the elderly and children**. A doctor should be consulted before use in a child under 5 years of age so that an ear wax problem can be confirmed.

2. BEFORE YOU USE OTEX OLIVE OIL

Do not use Otex Olive Oil:

- If you are **allergic (hypersensitive)** to Olive Oil.
- 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 you have had your ear syringed in the last 2-3 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 Otex Olive Oil gets into the eyes:

- Take care to avoid getting Otex Olive Oil 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 Olive Oil while you are putting anything else in the ear (such as other ear drops, ear medicines or a hearing aid).
- Otex Olive Oil 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 Olive Oil can be used during pregnancy and while breast-feeding. Olive oil has 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.

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3. HOW TO USE OTEX OLIVE OIL

Only use Otex Olive Oil in the ears.

For adults, the elderly and children (diagnosed with hardened ear wax):

Repeat the following once or twice daily, for up to 2 weeks, until you notice an improvement in your hearing and less discomfort:

- 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 the cap may pose a choking hazard. Following the first use, the dropper acts as a replacement for the original cap.
- Remove the dropper from the separate sachet and insert into bottle.
- Gently squeeze dropper to fill with Otex Olive Oil and hold.
- Tilt your head and gently release 2-3 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 dropper after use and return the bottle to the carton.

Note that in some cases excessive ear wax may persist for more than 14 days, despite softening. If the wax is very hard, the ear drops alone may not be able to clear the ear canal and any softening and expansion of the wax volume 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 Olive Oil than you should

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

If you forget to use Otex Olive Oil

Do not worry if you occasionally forget to use Otex Olive Oil. 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 drops, Otex Olive Oil 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 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 OTEX OLIVE OIL

- 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 or below 10°C.
- Always replace the dropper tightly after use.
- Store the bottle upright in the outer carton to avoid spillage.

6. FURTHER INFORMATION ABOUT OTEX OLIVE OIL

Otex Olive Oil contains EP grade Virgin Olive Oil.

What Otex Olive Oil looks like and contents of the pack

- The bottle contains 10 ml of Otex Olive Oil ear drops. The glass bottle is fitted with a screwcap and is supplied with a separate dropper.
- The product is a clear, yellow or greenish-yellow liquid.

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

This Leaflet was last approved in May 2021.

 Consult Instructions for Use

 Medical Device

 Batch Code

 Use-by Date

 Manufacturer