

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:

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

- Otex Olive Oil Ear Spray is used to help soften and remove hardened wax from the ear canal.
- Otex Olive Oil Ear Spray is 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.
- 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 Ear Spray makes removal of ear wax easier, and may avoid the need for ear syringing.

2. BEFORE YOU USE OTEX OLIVE OIL EAR SPRAY Do not use Otex Olive Oil Ear Spray:

- 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 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 spray.
- If you have had your ear syringed in the last 2 to 3 days - this could also make it painful to use the ear spray.

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 Ear Spray gets into the eyes:

- Take care to avoid getting Otex Olive Oil Ear Spray in the 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 Olive Oil Ear Spray while you are putting anything else in the ear (such as other ear drops, ear medicines or a hearing aid).
- Otex Olive Oil Ear Spray 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 Ear Spray 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 spray (see Section 4). If you are affected, do not drive or use machinery.

3. HOW TO USE OTEX OLIVE OIL EAR SPRAY

Only use Otex Olive Oil Ear Spray in the ears.

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

Before using a new bottle, hold the bottle upright and press the actuator (aiming at a tissue or similar) until you get a spray. This will prime the pump ready for use.

Repeat the following once or twice daily, for up to 14 days, until you notice an improvement in your hearing and less discomfort:

- Hold the bottle in an upright position with the nozzle placed at the entrance to the ear canal and spray once. Do not forcefully push into the ear canal as this may cause damage. Make sure you press down the actuator fully during each use.
- After spraying, tilt the head for a minute or two so that the fluid flows down into the ear canal.
- Leave for a few minutes then use a tissue to wipe away any surplus product that runs from the ear.
- Do not "plug" the ears with cotton wool.
- Repeat in the other ear, if necessary.
- Wash hands after use.
- Always return bottle to the carton after use.

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 spray alone may not be able to clear the ear canal and any softening and expansion of the wax volume may worsen the symptoms of excessive ear wax, including tinnitus and 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 Ear Spray than you should

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

If you forget to use Otex Olive Oil Ear Spray

Do not worry if you occasionally forget to use Otex Olive Oil Ear Spray. 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, nurse or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all ear sprays, Otex Olive Oil Ear Spray can cause side effects, although not everybody gets them.

 The ear spray 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 treating ear wax. Stop using Otex Olive Oil Ear Spray 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.

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 manufacturer (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 OLIVE OIL EAR SPRAY

- 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.
- Store the bottle upright in the outer carton to avoid spillage.

6. FURTHER INFORMATION ABOUT OTEX OLIVE OIL EAR SPRAY

Otex Olive Oil Ear Spray contains EP grade virgin olive oil.

What Otex Olive Oil Ear Spray looks like and contents of the pack

- Otex Olive Oil Ear Spray is presented in a 10 ml glass bottle with a spray pump.
- 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 revised in August 2024.

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- LOT Batch code
 - Use by date
 - Manufacturer