

Package Leaflet: Information for the user

Exterol[®] 5% w/w Ear Drops, solution

(urea hydrogen peroxide)

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.

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1 What Exterol is and what it is used for

- * Exterol ear drops are used to help remove hardened wax from the ear canal.
- * Exterol is suitable for use by **adults, children and the elderly**.
- * The **active ingredient** is urea hydrogen peroxide. It works by breaking down the ear wax into small 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.
 - * Exterol makes removal of ear wax easier, and in many cases avoids the need for ear syringing.

2 Before you use Exterol**Do not use Exterol:**

- * if you are **allergic (hypersensitive)** to urea hydrogen peroxide or any of the other ingredients of Exterol 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.
- * if you have had your ear syringed in the last 2 to 3 days – this could also make it painful to use the eardrops.

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 Exterol gets into the eyes

- * Take care to avoid getting Exterol into 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 into the other eye.
- * Tell your doctor or pharmacist if irritation persists.

Taking other medicines and using hearing aids

- * It is important not to use Exterol at the same time you are putting anything else in the ear (such as other ear drops or a hearing aid).
- * Exterol is not known to affect, or to be affected by, any other kinds of medicines that you may be using.

Pregnancy and breast-feeding

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

3 How to use Exterol

Only use Exterol in the ears.

For adults, children and the elderly: Repeat the following **once or twice daily, normally for 3 to 4 days**, 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 to reveal the applicator nozzle.
- * Tilt your head and gently squeeze up to 5 drops into the ear.
- * Keep your head tilted for a few minutes so that the drops stay in the ear.
- * Then wipe away any surplus with a tissue.
- * Repeat in the other ear, if necessary.
- * Wash hands after use.
- * **Do not** "plug" the ears with loose cotton wool.
- * Always replace the cap after use and return the bottle to the carton.

Note that in some cases excessive ear wax may persist for more than 3 to 4 days, despite softening. If the wax is very hard, the ear drops alone may not be able to clear the ear canal. This may cause some temporary loss of hearing.

In these cases you should consult your doctor, nurse or pharmacist for further advice.

Package Leaflet: Information for the user (continued)

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If you use more Exterol than you should

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

If you forget to use Exterol

Do not worry if you occasionally forget to use Exterol. 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 medicines, Exterol can cause side effects, although not everybody gets them.

- * A temporary mild bubbling sensation in the ear can occur (due to the release of oxygen as the drops break down the ear wax).
- * 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. 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Exterol

- * Keep this medicine out of the sight and reach of children.
- * Do not use this medicine after the expiry date which is stated on the bottle and carton. The expiry 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 cap tightly after use.
- * Store the bottle upright in the outer carton to avoid spillage.
- * Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Further information**What Exterol contains:**

The **active ingredient** is urea hydrogen peroxide (5% w/w). The **other ingredients** are 8-hydroxyquinoline and glycerol.

What Exterol looks like and contents of the pack

- * The bottle contains 8ml of Exterol ear drops. The plastic bottle is fitted with a dropper and screwcap.
- * The product is a clear, straw-coloured, viscous solution.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, B98 0RE, UK.

Manufactured by:

Fleet Laboratories Ltd, 94 Rickmansworth Road, Watford, Herts, WD18 7JJ, UK.

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Blind or partially sighted?

Is this leaflet hard to see or read?

Phone Lexon (UK) Limited, Tel: 01527 505414 for help.