PACKAGE LEAFLET: INFORMATION FOR THE USER

Cerumol Ear Drops Solution

Arachis oil refined (peanut oil) 57.3% w/v chlorobutanol hemihydrate 5% w/v

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Cerumol Ear Drops carefully to get the best results from it.

• Keep this leaflet. You may need to read it

- again.
- Ask your pharmacist if you need any more information or advice.
- · You must contact your doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- 1. What Cerumol Ear Drops are and what they are used for
- Before you use Cerumol Ear Drops How to use Cerumol Ear Drops
- Possible side effects
- How to store Cerumol Ear Drops
- Further information

1. What Cerumol Ear Drops are and what they are used for

Cerumol Ear Drops contains arachis oil refined to help lubricate the ear wax and chlorobutanol hemihydrate, an antibacterial agent, which also helps to loosen the wax.

This product is used to soften and help remove ear wax.

2. Before you use Cerumol Ear Drops

Do not use the medicine if you or your child have....

- An allergy to any of the ingredients listed in section 6 including peanut oil or soya.
- A sore or inflamed ear canal.
- Dermatitis or eczema on the outer ear.
- A perforated ear drum.

Take special care with Cerumol Ear Drops....

- Do not use for more than three days without talking to your doctor.
- Do not swallow the ear drops.

Pregnancy and breast-feeding... Ask your doctor or pharmacist for advice before using this medicine if you are pregnant, might be pregnant or are breastfeeding.

A Driving and using machines

There are no known effects on driving and using machines, but an ear wax plug may cause temporary deafness.

3. How to use Cerumol Ear Drops

For use in the ear.

Adults, the elderly and children:

- Prepare a small pad of cotton wool, the size of your thumb nail.
- Lie or sit down and tilt your head to the side.
 Use the dropper to put 5 drops into the ear
- . Do not push the dropper into your ear.
- As the liquid enters your ear you may experience a harmless tingling sensation.
- Moisten the small pad of cotton wool with Cerumol or smear with petroleum jelly.
- Place the cotton wool pad in the ear but do not push it too far into the ear canal. This helps to keep the liquid in the ear canal.
- Remove the pad after one hour or the next
- morning.

 Repeat twice a day for three days.

 The loosened wax usually comes out on its own, but if any wax remains, consult your doctor for possible syringing.

 • Do not use for longer than 3 days without
- consulting your doctor.





If you accidentally swallow Cerumol Ear Drops

See a doctor if you accidentally swallow some. Take the pack with you to show which medicine you have swallowed.

If you forget to use Cerumol Ear Drops

Use the ear drops as soon as you remember. You can then carry on the treatment at the correct time.

4. Possible side effects

Like all medicines, Cerumol Ear Drops can cause side effects, although not everybody gets

Possible side effects:

- Local irritation.
- · Redness. · Rash.
- If any of the side effects gets serious or you notice any side effect not included above, stop use and tell your doctor or pharmacist. They will tell you what to do.

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 via the following national reporting systems:

United Kingdom

Yellow Card Scheme – www.mhra.gov.uk/yellowcard

www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cerumol Ear **Drops**

- Keep out of the sight and reach of children.
- No special storage precautions are necessary for the unopened pack.
- Do not use after the expiry date shown on the carton. The expiry date refers to the last day of that month.
- Once opened, use within 6 months.
- · Medicine should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What is in this medicine The active ingredients are:

Arachis oil refined (peanut oil) 57.3% w/v, chlorobutanol hemihydrate 5% w/v.

The other ingredients are:

turpentine oil, 3-methoxy butyl acetate, σ -dichlorobenzene, p-dichlorobenzene.

What the medicine looks like

Cerumol Ear Drops are a pale amber oily liquid which smells of turpentine. They are supplied in 11ml bottles.

Marketing authorisation holder and manufacturer

Thornton and Ross Ltd., Huddersfield, HD7 5QH, UK.

Cerumol is a trade mark of Thornton and Ross I td.