

Package leaflet: Information for the user

EarCalm Spray

Acetic acid 2%

Please read right through this leaflet before you start using this medicine. This medicine is available without prescription, but you still need to use EarCalm carefully to get the best results from it.

- Keep this leaflet you may need to read it again.
- If you have any further questions, ask your pharmacist.
- **Do not use for more than 7 days.**

In this leaflet:

1. What EarCalm does
2. Check before you use EarCalm
3. How to use EarCalm
4. Possible side effects
5. How to store EarCalm
6. Further information

1. What EarCalm does

EarCalm is used for the treatment of minor infections of the outer ear.
The active ingredient is acetic acid, an antibacterial agent that helps clear such infections.

2. Check before you use EarCalm

Do not use EarCalm:

- if you have ever had an allergic reaction to acetic acid or any of the other ingredients (listed in Section 6)
- if you are under 12 years
- anywhere other than in the ear. Do not inhale in the mouth or nose or spray near the eyes.

Take special care with EarCalm

- If you have a perforated eardrum, or if you think you may have, consult your doctor before you use this medicine.
- Stop treatment and call your doctor:
 - If you get any pain
 - If symptoms worsen or do not improve within 48 hours
 - If hearing is affected.
- Do not use for more than 7 days.

3. How to use EarCalm

Before using a new bottle of EarCalm

- Shake well before use.
- Press the pump down several times until you get a fine spray
- Make sure you do not point the nozzle at yourself or someone else
- The bottle is now ready for use
- Each time the pump is pressed down one measured dose will be delivered

- If you have not used EarCalm for more than a week, press the pump a few times until you get a fine spray again, and then follow the instructions above.

For external use only.

Using EarCalm

- Shake well before use
- Place the nozzle tip gently into your ear
- Press the pump once to deliver the measured dose
- Spray one measured dose into each affected ear at least three times a day (morning, evening and after swimming, showering or bathing), or as directed by your doctor/pharmacist
- Leave at least 2 to 3 hours between doses
- Continue treatment until two days after symptoms have disappeared, but no longer than 7 days
- If you forget to use EarCalm do not worry. Use it as soon as you remember then go on as before
- The nozzle tip must be in place when you use the spray. You can remove it for cleaning but always click it back into place afterwards
- After use, wipe the nozzle tip with a tissue to remove any ear wax residue.

4. Possible side effects

Like all medicines, EarCalm can have side effects, but not everybody gets them:

- sensitivity or allergy. If this happens, stop using the spray.
- Temporary stinging or a burning sensation for the first few days of treatment

If you do get any side effects, even those not mentioned in this leaflet, tell your doctor or pharmacist.

5. How to store EarCalm

Keep out of the reach and sight of children.

Do not use this medicine after the 'EXP' date shown on the pack.

Do not store above 25°C.

Keep container upright in the outer carton.

Use within one month of first use.

6. Further information

Active ingredient 2% w/w Acetic Acid (glacial).

Other ingredients Macrogol stearyl alcohol, stearyl alcohol, methyl parahydroxybenzoate (E 218), propyl parahydroxybenzoate (E 216), purified water.

EarCalm is supplied in packs containing 5ml as an aqueous suspension. The spray is non-pressurised and does not contain CFCs.

The Marketing Authorisation Holder is Forest Laboratories UK Ltd, Dartford, Kent, DA2 6SL, UK and all enquiries should be sent to this address.

The Manufacturer is Purna Pharmaceuticals NV, Rijksweg 17, 2870 Puurs, Belgium.

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