

Package leaflet: Information for the user

Tropex[®] 5% w/v Ear Drops Solution

Phenazone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must contact a doctor if you do not feel better or if you feel worse after 24 hours.

What is in this leaflet:

1. What Tropex is and what it is used for
2. What you need to know before you use Tropex
3. How to take Tropex
4. Possible side effects
5. How to store Tropex
6. Contents of the pack and other information

1. What Tropex is and what it is used for

Tropex Ear drops solution contains phenazone which is an analgesic (painkiller) and an anti-inflammatory agent. Tropex is used to provide relief of the symptoms associated with inflammation of the ear. Glycerol is used to soften and remove any ear wax.

2. What you need to know before you use Tropex

Do not use Tropex:

- If you have a perforated (burst) ear drum
- If you are allergic to phenazone or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Tropex.

If improvement does not occur within 24 hours consult your doctor. If there is an infection present consult your doctor.

Other medicines and Tropex

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Tropex is unlikely to interfere with other medicines; however, accidental swallowing of Tropex may affect the metabolism of medicines broken down by liver enzymes. Little absorption is expected from topical application into the ear canal.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

No effect on ability to drive or use machines is to be expected.

Tropex contains methyl parahydroxybenzoate.

May cause allergic reactions (possibly delayed).

3. How to take Tropex

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Tropex is for auricular use (administer the product into the ear). Usually 4-6 drops should be introduced into the ear 3-4 times daily according to the severity of the inflammation. You should check with your doctor or pharmacist if you are not sure.

In case of accidental oral intake

If you swallow small amounts of Tropex it will usually not cause any problem. However, for safety reasons, you should contact your doctor or pharmacist.

If you forget to use Tropex

Use the ear drops as soon as you remember then continue on as before.

If you have any further questions on the use of this product contact your doctor or pharmacist

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Phenazone may give rise to skin eruptions and hypersensitivity (allergic) reactions.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 Tropex

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on both the label of the bottle and the outer carton after EXP. The expiry date refers to the last day of the month.

Store Tropex in the original container.

Do not store above 25°C. Do not refrigerate.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Tropex contains

- The active substance is phenazone 5.0% w/v (50mg/ml).
- The other ingredients are methyl parahydroxybenzoate (E218) and glycerol.

What Tropex looks like and contents of the pack

Tropex Ear Drops is a clear colourless solution.

Tropex Ear Drops is available in a 10ml amber glass bottle equipped with dropper cap.

Marketing Authorisation Holder and Manufacturer

Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland

This leaflet was last revised in March 2015.