

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tropex[®] 5% w/v Ear Drops Solution

PHENAZONE

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 Tropex 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 more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 24 hours.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Tropex Ear Drops is and what it is used for
2. Before you use Tropex Ear Drops
3. How to use Tropex Ear Drops
4. Possible side effects
5. How to store Tropex Ear Drops
6. Further Information

1. What Tropex Ear Drops is and what it is used for

These ear drops contain Phenazone which is an analgesic (painkiller) and an anti-inflammatory agent. Tropex Ear Drops 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. Before you use Tropex Ear Drops

Do not use Tropex Ear Drops:

- if you have a perforated (burst) ear drum
- if you are allergic (hypersensitive) to Phenazone or any of the other ingredients of Tropex Ear Drops (see section 6 "Further Information" for details).

Take special care with Tropex Ear Drops

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

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Tropex Ear Drops 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

There is no reason that you should stop the use of Tropex Ear Drops during pregnancy or lactation.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

Important information about some of the ingredients of Tropex Ear Drops

This medicine contains Methyl Parahydroxybenzoate which may cause allergic reactions (possibly delayed).

3. How to use Tropex Ear Drops

Tropex Ear Drops 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 Ear Drops it will usually not cause any problem. However, for safety reasons, you should contact your doctor or pharmacist.

If you forget to use Tropex Ear Drops

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, Tropex Ear Drops can cause side effects, although not everybody gets them.

Phenazone may give rise to skin eruptions and hypersensitivity (allergic) reactions.

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.

5. How to store Tropex Ear Drops

Keep out of the reach and sight of children.

Do not use Tropex Ear Drops 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 Ear Drops 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 dispose of medicines no longer required.

These measures will help to protect the environment.

6. Further Information

Tropex Ear Drops contains

- The active substance is Phenazone 5.0% w/v (50mg/ml).
- The other ingredients are Methyl Parahydroxybenzoate (E218) and Glycerol.

What Tropex Ear Drops 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 approved in March 2009

Artwork Checklist

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