

Otocomb Otic*

Triamcinolone acetonide, neomycin as sulphate,
gramicidin & nystatin

Consumer Product Information

What is in this leaflet

Read this leaflet carefully before using Otocomb Otic. This leaflet answers some common questions about Otocomb Otic. It does not contain all the available information. Some of the information it contains may not apply to you. It does not take the place of talking to your doctor or pharmacist. Do not throw this leaflet away. You may need to refer to it again later.

Always follow the instructions that your doctor or pharmacist give you about Otocomb Otic.

If you have any concerns about using Otocomb Otic, ask your doctor or pharmacist.

What Otocomb Otic is used for

Otocomb Otic is used to relieve itching, burning or inflammation of the ear, when it is infected or if it is inflamed and sore and likely to get infected.

Otocomb Otic is the trade name (manufacturer's name) for ear drops or ointment, Produced by Bristol Laboratories,

containing the drugs triamcinolone acetonide, neomycin, gramicidin and nystatin.

Triamcinolone acetonide belongs to a class of drugs called corticosteroids, which help to relieve itching, burning, inflammation and allergic effects.

Neomycin and gramicidin are antibiotics. They kill the bacteria that may be causing your infection.

Nystatin is an antifungal drug. It is used to kill any fungi that may be present, or that may grow when antibiotics are being used.

Your doctor will need to look inside your ears, especially at your eardrums and may clean your ears before prescribing Otocomb Otic.

Before you use Otocomb Otic

When you must not use it -

- Do not use Otocomb Otic if you are pregnant or may become pregnant.
- Otocomb Otic must not be used in your eyes.
- You should not apply Otocomb Otic to sores or cuts.
- Do not use Otocomb Otic if you have ever had an allergic reaction to any of the ingredients listed at the end of this leaflet.

- Do not use Otocomb Otic after the expiry date has passed. The expiry date is printed on the label of the ear drops or on the flat end of the ointment tube.
- Do not use Otocomb Otic if the protective seal on the Bottle or Tube has been broken.

Before you start to use it -

You must tell your doctor if you:

- are pregnant or may become pregnant
- are allergic to any medicines, foods, dyes or preservatives.
- have recently had any infections with herpes simplex, chicken pox or tuberculosis, or any other recent infections
- have dizziness or any problems with hearing
- have had any recent injury to your eardrums.
- if you are taking any other medicines even if it was bought without a prescription

Using other medicines

It is unlikely that other medicines will affect the way Otocomb Otic works.

Nevertheless, you should always tell your doctor about other medicines you are taking, even if you have bought the medicines without a prescription.

How to use Otocomb Otic

Otocomb Otic should only be used as directed by your doctor.

It is important that you always follow your doctor's instructions about how much Otocomb Otic to use, how often you should use it, and for how long.

How to apply Otocomb Otic-

Ear Drops: put two or three drops into the ear, two or three times daily.

Ointment: Gently and carefully insert the tapered tip of the tube into the ear canal and squeeze out a little of the ointment, two or three times a day.

If your condition gets worse or does not get better while using Otocomb Otic, stop using it and tell your doctor straight away. You may need a different antibiotic medication.

How long to use Otocomb Otic

Your doctor or pharmacist will tell you how long you need to use Otocomb Otic.

If you forget to use Otocomb Otic

If you forget to apply a dose of Otocomb Otic, put in the next dose at the usual time and in the normal amount. Do not use any more than your doctor has prescribed.

If you swallow Otoplast Otic

Telephone your doctor or the Poisons Information Centre (Phone 13 11 26) if anyone swallows Otoplast Otic.

While you are using Otoplast Otic

Things you must do

Tell your doctor if you become pregnant while using Otoplast Otic.

Stop using Otoplast Otic and tell your doctor if your condition gets worse, or if you have difficulty hearing or have ringing in the ears while using it.

If you think that the packaging for Otoplast Otic is faulty or has been tampered with, do not use Otoplast Otic and show it to your pharmacist.

Things you must not do

Do not put Otoplast Otic into your eyes.

Do not swallow Otoplast Otic.

Do not put Otoplast Otic onto skin that is cut or bleeding.

Side Effects

All medications, including Otoplast Otic, can sometimes cause unwanted effects. Side effects of Otoplast Otic are rare, but may include:

- new itchiness or redness in areas where you apply Otocomb Otic
- ringing in the ears
- hearing difficulty
- damage to the ear drums
- slow wound healing
- disturbances of metabolism

If you have any of these effects or any other problem which worries you while using Otocomb Otic, tell your doctor as soon as possible.

After using Otocomb Otic

Storage

Ear Drops should be stored in a refrigerator, but not a freezer.

Ointment should be stored in a cool, dry place.

Keep all medicines out of reach of children.

Product description

What it looks like

Otocomb Otic is available either as ear drops or as an ointment.

The Ear Drops are a yellow coloured oily liquid packed in a dropper bottle, 7.5mL. (AUST R 56477).

The Ointment is a yellow coloured ointment packed in a tube with a cannula tip, 5g. (AUST R 56460).

Active ingredients

Each gram of Otocomb Otic contains :

- triamcinolone acetonide 1mg
- neomycin 2.5mg as the sulphate
- gramicidin 0.25mg
- nystatin 100,000 units.

Inactive Ingredients

Liquid paraffin

Polyethylene

Further information

Otocomb Otic is only available on prescription from your doctor.

Never let anyone else use medicine that has been prescribed for you.

This leaflet was produced based on information known by Bristol-Myers Squibb Australia Pty Ltd in May 1996. Your

doctor will have access to information on any changes which may affect you.

Manufacturer

Otocomb Otic is made by

Bristol-Myers Squibb Australia Pty Ltd,

ACN 004 333 322,

556 Princes Highway,

Noble Park VIC 3174,

Australia.

and distributed by

Bristol Laboratories a division of

Bristol-Myers Squibb Australia Pty Ltd

Telephone (03) 9213 4000

*Trademark. 'Otocomb Otic' is a Bristol-Myers Squibb Company trademark

This information in no way replaces the advice of your doctor or pharmacist.