

OTOCOMB® OTIC ear drops and ointment

triamcinolone acetonide, neomycin (as sulfate), gramicidin & nystatin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about OTOCOMB OTIC. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

Always follow the instructions that your doctor or pharmacist give you about OTOCOMB OTIC.

Ask your doctor or pharmacist if you have any concerns about using this medicine.

Do not throw this leaflet away. You may need to refer to it again later.

What OTOCOMB OTIC is used for

OTOCOMB OTIC is available in either ear drops or ointment forms and is used to relieve itching, burning, pain or inflammation of the outer ear and ear canal when it is infected or likely to be infected. It contains a combination of medicines:

- triamcinolone acetonide, belongs to a class of drugs called corticosteroids, which helps to relieve itching, inflammation and redness.
- neomycin, is an antibacterial medicine
- gramicidin, is an antibacterial medicine.
- nystatin, is an antifungal drug. It is used to prevent or treat a

particular type of fungal infection called *Candida albicans*.

Your doctor will need to look inside your ears, especially at your eardrums and may have to clean your ears before prescribing this medicine.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

OTOCOMB OTIC is only available on prescription from your doctor.

Use in Children

OTOCOMB OTIC should be used carefully in children. Long term use can cause systemic side effects through absorption of OTOCOMB OTIC.

Before you use it

When you must not use it

Do not use OTOCOMB OTIC if you have an allergy to:

- any medicine containing nystatin, neomycin, gramicidin, triamcinolone acetonide
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

- rash, itching or hives on the skin.

Do not use this medicine if you have any of the following medical conditions:

- viral infections such as shingles, chicken pox or cold sores
- tuberculosis.

Do not use OTOCOMB OTIC to treat a middle ear infection.

Do not use this medicine if your ear drums are perforated.

Do not use it in the eyes.

Do not use after the expiry date has passed.

Do not use it if the protective seal on the bottle or tube has been broken.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have extensive skin damage or other conditions where absorption of neomycin is possible.

Tell your doctor if you are pregnant or plan to become pregnant.

Tell your doctor if you are breast feeding or plan to breast feed.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start to use OTOCOMB OTIC.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and OTOCOMB OTIC may interfere with each other. Your doctor or pharmacist may have more information on which medicines to be careful with or to avoid while using OTOCOMB OTIC.

How to use it

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 it

Ear Drops:

Shake well before use.

Squeeze two or three drops into the ear canal, two or three times daily. Alternatively, a gauze wick saturated with the drops may be inserted in the ear canal.

Ointment:

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

The ointment can also be applied to the outer ear if required.

How long to use it

Your doctor will tell you how long you need to use OTOCOMB OTIC.

Even if symptoms improve within the first few days of treatment, you should not interrupt or stop OTOCOMB OTIC until the

prescribed course of treatment has been completed.

If you forget to use it

If you forget one or more applications, do not apply more than the usual amount to make up for the missed dose.

If you do, this may increase the chance of you getting an unwanted side effect.

At the next application time, apply the normal amount and continue the course of treatment.

Tell your doctor if for any reason you have not used OTOCOMB OTIC exactly as prescribed.

If you swallow it or if you apply too much (overdose)

If you apply too much or swallow it accidentally, immediately call your doctor or the Poisons Information Centre (phone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are using it

Things you must do

Tell all doctors and pharmacists who are treating you that you are using OTOCOMB OTIC, especially if you are about to start taking any new medicines.

Tell your doctor if your symptoms do not improve or they get worse.

Tell your doctor if you become pregnant while using OTOCOMB OTIC.

Things you must not do

Do not use OTOCOMB OTIC to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use it in your eyes.

Do not swallow it.

Do not use OTOCOMB OTIC on damaged skin.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using OTOCOMB OTIC.

All medicines, including OTOCOMB OTIC, can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Other side effects not listed below may also occur in some people.

Side effects with OTOCOMB OTIC are uncommon.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- itching, burning, dryness
- irritation
- excessive hair growth
- spots that look like acne
- skin rash
- changes in the colour of the skin
- stretch marks
- slow wound healing.

Tell your doctor as soon as possible if you notice any of the following:

- ringing in the ears
- hearing difficulties
- problems with your balance
- severe fluid retention
- passing less urine than normal.

Stop using OTOCOMB OTIC and tell your doctor immediately or go to the Accident and Emergency Centre at your nearest hospital if you notice any of the following:

- shortness of breath
- wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

If you have any of these symptoms, you may be experiencing an allergic reaction to OTOCOMB OTIC and may need urgent medical attention.

When used in children

Some of the side effects that may occur include:

- delayed weight gain and growth
- headaches
- bulging soft spots on skull.

Some side effects of OTOCOMB OTIC can only be found when your doctor does tests from time to time to check your progress.

After using it

Storage

Ear drops:

Store at 2 - 8°C in a refrigerator. Do not freeze.

Ointment:

Store below 25°C.

Keep all medicines out of reach of children.

Disposal

If your doctor tells you to stop using OTOCOMB OTIC, or if it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

OTOCOMB OTIC is available either as ear drops or as an ointment.

Ear drops:

A yellow coloured oily liquid in a plastic dropper bottle.

Ointment:

A yellow to amber coloured ointment in a 5 g tube with a cannula tip.

Ingredients

Active ingredients

OTOCOMB OTIC ear drops contains:

- triamcinolone acetonide 0.9 mg/mL
- neomycin sulfate 2.25 mg/mL
- gramicidin 0.225 mg/mL
- nystatin 90,000 IU/mL.

OTOCOMB OTIC ointment contains:

- triamcinolone acetonide 1 mg/g
- neomycin sulfate 2.5 mg/g
- gramicidin 0.25 mg/g
- nystatin 100,000 IU/g.

Inactive ingredients

- liquid paraffin
- polyethylene.

Sponsor

Aspen Pharma Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia

Australian Registration Numbers:
Ear drops: AUST R 56477
Ointment: AUST R 56460.

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