

Otodex[®]

Framycetin sulfate (fra-me-see-tin sul-fate), Gramicidin (grammy-sigh-din), Dexamethasone (dex-ar-meth-ar-sone)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Otodex.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you using Otodex against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Otodex is used for

Otodex is a medicine used to treat infection or inflammation of the ear. Otodex contains antibiotics (framycetin sulfate and gramicidin) to kill germs and a corticosteroid (dexamethasone) to stop inflammation, itching and weeping.

This medicine is available only with a doctor's prescription.

Before you use it

When you must not use it

Do not use Otodex if you have an allergy to Otodex or any of the

ingredients listed at the end of this leaflet.

Do not use Otodex if you are allergic to framycetin, gramicidin or dexamethasone.

Do not use Otodex if you have:

- a hole in your eardrum
- viral or tubercular lesions
- chicken pox (varicella virus)
- vaccinia - a type of virus

Do not use Otodex if you are pregnant or intend to become pregnant.

Like most aminoglycosides, Otodex is not recommended for use during pregnancy.

Do not use Otodex after the expiry date (EXP) printed on the pack.

If you use this medicine after the expiry date has passed, it may not work as well.

Do not use Otodex if the packaging is torn or shows signs of tampering, or if it doesn't look quite right.

If you are not sure whether you should start using Otodex, contact your doctor or pharmacist.

Before you start to use it

Tell your doctor or pharmacist if you have allergies to:

- framycetin, gramicidin or dexamethasone
- any other medicines, especially antibiotics such as neomycin, paromomycin and kanamycin
- any other substances, such as foods, preservatives or dyes

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

Like most medicines of this kind, Otodex is not recommended to be used during pregnancy. Your doctor or pharmacist will discuss the risks and benefits of using it if you are pregnant.

Taking other medicines

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

How to use it

Use Otodex only as directed by your doctor. Generally this will be as follows:

The drops are usually used 3 or 4 times daily. Remove the cap from the bottle immediately before use and place it back on the bottle immediately after use. To use the drops, tilt your head so that the affected ear is uppermost. Position the rubber dropper, which is attached to the bottle, directly above the ear hole. With the bottle tipped upside down, gently squeeze the rubber dropper until 2 or 3 drops fall into the ear. Keep your head tilted for about a minute to allow the drops to penetrate deep into the ear.

Your doctor may decide to adjust your dosage if necessary or ask you to use Otodex in a different way, according to his or her judgment.

Ask your pharmacist for advice if you need further instructions on how best to use Otodex.

How long to use it

Continue using Otodex until your doctor or pharmacist tells you to stop.

Do not stop using it unless your doctor or pharmacist tells you to - even if you feel better.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use it as soon as you remember, and then go back to using your medicine as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

While you are using it

Things you must do

Use Otodex only in the ear unless your doctor advises differently. Contact your doctor promptly if:

- your condition worsens during treatment
- an allergic reaction develops
- you feel no better after completing the prescribed treatment

If you become pregnant while using Otodex, stop using it and tell your doctor or pharmacist immediately.

Things you must not do

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

Do not use Otodex to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop using Otodex, or lower the dosage, without checking with your doctor or pharmacist.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Otodex, even if the problem is not listed below.

Otodex helps most people with an infection or inflammation of the ear, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not.

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

- local allergic reaction: pain, itching, stinging, weeping or swelling around the site of application

These are the more common side effects of Otodex. Mostly these are mild and short-lived.

Other side effects not listed above may occur in some patients.

After using it

Storage

Keep Otodex in a cool dry place where the temperature stays below 25°C. Do not refrigerate.

Do not store Otodex or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop using Otodex or the medicine has passed its expiry date, ask your pharmacist what to do with any that is left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Otodex Ear Drops is supplied as a sterile clear solution in a glass dropper bottle.

Ingredients

Active ingredients:

- framycetin sulfate (5 mg/mL)
- gramicidin (0.05 mg/mL)
- dexamethasone 0.5 mg/mL)

Inactive ingredients:

- phenethyl alcohol (preservative)
- polysorbate 80
- industrial methylated spirit
- citric acid monohydrate
- sodium citrate dihydrate
- lithium chloride
- sodium hydroxide
- hydrochloric acid
- purified water

Supplier

Otodex is supplied in Australia by:
sanofi-aventis australia pty ltd
12-24 Talavera Road
Macquarie Park NSW 2113

This leaflet was prepared in April 2020.

Australian Registration Number

Otodex Ear Drops: AUST R 43840

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