

OTOMIZE EAR SPRAY

dexamethasone,
neomycin sulfate,
acetic acid



Package leaflet: Information for the patient

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

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

1. What Otomize is and what it is used for

Otomize is used to treat infection and inflammation of the outer ear.

Otomize contains three active ingredients. Dexamethasone is a topical corticosteroid medicine which is used to control inflammation. Neomycin sulfate is a broad spectrum antibiotic to fight infections and acetic acid is an antibacterial agent that also helps to clear infections.

2. What you need to know before you use Otomize



Do not use Otomize:

- **if you** are allergic to dexamethasone, neomycin sulfate, acetic acid or to any of the other ingredients of this medicine (listed in Section 6).
- **anywhere other than in the ear.** Do not inhale in the mouth or nose or spray near the eyes.

- **if you have a perforated ear drum** or have a grommet fitted in the affected ear.
- in children under 2 years of age



Warnings and precautions

Talk to your doctor or pharmacist before using Otomize.

- If you know (or think you have) a mitochondrial disease (mutations in the parts of your cells which help make energy); certain mitochondrial diseases may increase your risk of hearing loss with this product.
- Excessive use (high doses or prolonged use) of this product on open wounds or damaged skin may cause deafness. This is particularly important to consider when used on children.
- **Do not swallow any of the spray.** If swallowed (especially by a child) contact your **doctor or casualty department immediately.**
- Contact your doctor if you experience blurred vision or other visual disturbances.

Children

Not to be used in children under 2 years of age.



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.

Otomize contains methyl and propyl hydroxybenzoates, and stearyl alcohol

This medicine contains methyl and propyl hydroxybenzoates (E218 and E216) which may cause allergic reactions (possibly delayed). It also contains stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

3. How to use Otomize

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Before using a new bottle of Otomize:

- **Shake well before use.**
- **Press the pump down several times** until you get a fine spray.
- Make sure you do not point the nozzle at yourself or someone else.
- Each time the pump is pressed down one measured dose will be delivered.
- **If you have not used Otomize for more than a week**, press the pump a few times until you get a fine spray again, and then follow the instructions above.

For external use only.



Using Otomize:

Adults and children over the age of 2 years.

- **Shake well before use.**
- **Place the nozzle tip** gently into your ear.
- **Press the pump once** to deliver the correct dose.
- **Spray one measured dose into each affected ear three times a day**, or as directed by your doctor.
- **If you forget to use Otomize do not worry.** Use it as soon as you remember then go on as before.
- **The nozzle tip must always be in place** when you use the spray. You can remove it for cleaning but always click it back into place afterwards.



- **Continue using Otomize until two days after symptoms have gone.**
- **Stop using the product and consult a doctor if your condition worsens or does not improve after 7 days treatment.**
- **Do not use more than the recommended dose.**

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using the medicine and tell your doctor if you experience:

- Sensitivity or allergic reactions (irritation or a rash).

The following side effects may also occur, but usually go away after the first few days of treatment:

- Temporary stinging or a burning sensation.

The following side effect has also been reported:

- Blurred vision

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Otomize

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

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

Do not store above 25°C. Do not freeze. Keep container upright in the outer carton.

Use within one month of first use.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Otomize contains

The active substances are Dexamethasone 0.1% w/w, Neomycin Sulfate 0.5% w/w (3250 IU/ml), Acetic Acid (glacial) 2.0% w/w.

The other ingredients are Macrogol (2) stearyl ether, macrogol (20) stearyl ether, stearyl alcohol, methyl parahydroxybenzoate (E 218), propyl parahydroxybenzoate (E 216) and purified water.

What Otomize looks like and contents of the pack

Otomize is a milky oil-in-water emulsion supplied in a 5 ml amber glass bottle fitted with a spray device. The spray is non-pressurised and does not contain CFCs.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.

The manufacturer is Purna Pharmaceuticals NV, Rijksweg 17, 2870 Puurs, Belgium.

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