

OTOMIZE[®] EAR SPRAY

(dexamethasone / neomycin sulphate / glacial acetic acid)

The medicine is known by the above name but will be referred to as Otomize throughout this leaflet.

Patient Information Leaflet

Please read right through this leaflet before you start using this medicine. This medicine is available on prescription only.

- Keep this leaflet you may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.

In this leaflet:

1. What Otomize does
2. Check before you use Otomize
3. How to use Otomize
4. Possible side effects
5. How to store Otomize
6. Further information

1. What Otomize does

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 sulphate is a broad spectrum antibiotic to fight infections and acetic acid is an antibacterial agent that also helps to clear infections.

2. Check before you use Otomize

Do not use Otomize:

- if you have ever had an allergic reaction to dexamethasone, neomycin sulphate, acetic acid or to any of the other ingredients (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.

Take special care with Otomize

- 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.

Pregnancy and breast feeding

Talk to your doctor before using Otomize if you are pregnant, trying to become pregnant, or breast feeding.

3. How to use Otomize

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, Otomize can have side effects, but not everyone 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.

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. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Otomize

Keep out of the sight and reach of children.

Do not store above 25°C. Do not freeze. Store the spray upright in the carton. Do not use the spray after the expiry date printed on the carton or bottle label. Use within one month of first use.

If the spray becomes discoloured or show any signs of deterioration you should seek the advice of your pharmacist.

If your doctor tells you to stop taking this medicine, please return any leftover spray to the pharmacist for safe disposal. Only keep the spray if your doctor tells you to.

6. Further information

What is in your medicine?

The name of your medicine is Otomize. Otomize is a milky liquid ear spray in a glass bottle. It is an emulsion for application to the external ear canal. The spray is non-pressurised and does not contain CFCs. This pack contains 5ml as an aqueous suspension.

Each ml contains dexamethasone 0.1% w/w, neomycin sulphate 0.5% w/w (3250 IU/ml) and glacial acetic acid 2% w/w.

Dexamethasone is an anti-inflammatory agent. Neomycin sulphate is a broad spectrum antibiotic. Glacial acetic acid is an anti-bacterial agent and pH adjuster.

Your medicine also contains the following inactive ingredients: macrogol (2) stearyl ether, macrogol (20) stearyl ether, stearyl alcohol, methyl parahydroxybenzoate (E218) propyl parahydroxybenzoate (E216) and purified water.

Otomize is manufactured by Purna Pharmaceuticals, Belgium and is procured from within the EU by the Product Licence Holder: Caseview (PL) Limited, 20 Alliance Court, Alliance Road, London W3 0RB and repackaged by O.P.D. Laboratories Ltd., Unit 6 Colonial Way, Watford, Herts WD24 4PR.

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Otomize® Ear Spray

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