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Otrivine[®]
Adult Mucus Relief
Menthol 0.1% w/v
 Nasal Spray
 Xylometazoline
 Hydrochloride

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

This medicine is available without a prescription. However, you still need to use Otrivine Adult Mucus Relief Menthol 0.1% w/v Nasal Spray carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet.
- You must talk to a doctor if the symptoms worsen or do not improve after 7 days.

In this leaflet:

1. What Otrivine Adult Mucus Relief Menthol 0.1% w/v Nasal Spray is and what it is used for
2. Before you use Otrivine Adult Mucus Relief Menthol 0.1% w/v Nasal Spray
3. How to use Otrivine Adult Mucus Relief Menthol 0.1% w/v Nasal Spray
4. Possible side effects
5. How to store Otrivine Adult Mucus Relief Menthol 0.1% w/v Nasal Spray
6. Further information

1. WHAT OTRIVINE ADULT MUCUS RELIEF MENTHOL 0.1% W/V NASAL SPRAY IS AND WHAT IT IS USED FOR

Otrivine Adult Mucus Relief Menthol 0.1% w/v Nasal Spray is for application in the nose to give relief from:

- nasal congestion (blocked nose, including colds)
- perennial and allergic rhinitis (recurring inflammation of the nasal mucous membranes, including hay fever)
- sinusitis.

Otrivine Adult Mucus Relief Menthol 0.1% w/v Nasal Spray contains the active ingredient xylometazoline hydrochloride which helps to open up and clear the nasal passages

by reducing the excessive nasal secretions and returning the swollen blood vessels to their normal size.

2. BEFORE YOU USE OTRIVINE ADULT MUCUS RELIEF MENTHOL 0.1% W/V NASAL SPRAY

DO NOT use the spray if you:

- are allergic to xylometazoline hydrochloride or any of the other ingredients in the spray (see Section 6)
- have had recent neurosurgery
- have narrow angle glaucoma.

Do not use this spray for children under 12 years old.

Take special care

Before using the spray tell your doctor if you:

- have high blood pressure, heart or circulatory disease
- have an overactive thyroid
- have diabetes mellitus
- are pregnant or breast-feeding.

Do not take decongestants for more than 7 days in a row.

Using other medicines

You should not use Otrivine Adult Mucus Relief Menthol 0.1% w/v Nasal Spray if you are taking certain medicines used for treatment of depression (monoamine oxidase inhibitor (MAOI) or tri-cyclic and tetra-cyclic antidepressants). Please tell your doctor or pharmacist if you are taking or have recently taken any medicines including those obtained without a prescription.

Pregnancy or breast-feeding

Do not use Otrivine Adult Mucus Relief Menthol 0.1% w/v Nasal Spray during pregnancy.

If you are breast-feeding, Otrivine Adult Mucus Relief Menthol 0.1% w/v Nasal Spray should only be used if recommended by your doctor.

Important information about some of the other ingredients:

This medicine contains polyoxyl hydrogenated castor oil (2.750 mg/ml) which may cause skin reactions.

3. HOW TO USE OTRIVINE ADULT MUCUS RELIEF MENTHOL 0.1% W/V NASAL SPRAY

For Adults and Children over 12 years of age:

one spray in each nostril up to 3 times daily as needed.

Administration

1. Blow your nose gently.
2. Remove protective cap.
3. Do not cut the nozzle.

The metered dose spray is ready to prime before use.

4. Before the first application, prime the pump by actuating (depressing the pump) 4 times. Once primed the pump will normally remain charged throughout regular daily treatment periods.



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- Should the spray not be ejected during the full actuation, the pump will need to be re-primed by actuating 4 times. Be very careful not to spray in the eyes or mouth.
5. Hold the bottle upright with thumb under base and nozzle between two fingers.
 6. Lean forward slightly and insert the nozzle into the nostril.
 7. Spray and breathe in gently through the nose at the same time.
 8. Repeat with the other nostril.
 9. Clean and dry the nozzle before replacing back the cap right after use.



To avoid possible spread of infection, this pack should only be used by one person.

Do not exceed the recommended dosage.

If you use more Otrivine Adult Mucus Relief Menthol 0.1% w/v Nasal Spray than you should, consult your doctor or pharmacist.

If you forget to use Otrivine Adult Mucus Relief Menthol 0.1% w/v Nasal Spray
Do not take a double dose to make up for a forgotten one.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Otrivine Adult Mucus Relief Menthol 0.1% w/v Nasal Spray can cause side effects, although not everybody gets them. Local discomfort may be felt after applying the spray if you have sensitive nasal passages.

STOP using Otrivine Adult Mucus Relief Menthol 0.1% w/v Nasal Spray and **seek medical help immediately** if you have any of the following which may be signs of an allergic reaction:
difficulty breathing or swallowing, swelling of the face, lips, tongue or throat severe itching of the skin, with a red rash or raised bumps.

Common side effects (may affect between 1 and 10 in every 100 patients).
Dryness or irritation of the nasal mucosa, nausea, headache, local burning sensation.

Very rare side effects (may affect less than 1 in every 10,000 patients).
Allergic reactions (skin rash, itching), blurred vision, irregular or fast heartbeat.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517;
Website: www.hpra.ie;
E-mail: medsafety@hpra.ie.

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

5. HOW TO STORE OTRIVINE ADULT MUCUS RELIEF MENTHOL 0.1% W/V NASAL SPRAY

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

Do not use after the expiry date which is stated on the bottle and carton after 'EXP'.
The expiry date refers to the last day of that month.
Do not store above 25 °C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Otrivine Adult Mucus Relief Menthol 0.1% w/v Nasal Spray contains

The active ingredient is Xylometazoline hydrochloride (0.1% w/v). Each ml contains 1 mg of xylometazoline hydrochloride.

The **other ingredients** are: Sodium dihydrogen phosphate dihydrate, disodium phosphate dodecahydrate, sodium chloride, disodium edetate, levomenthol (Menthol), cineole (Eucalyptol), sorbitol, polyoxylhydrogenated castor oil (macrogol glycerol hydroxystearate) and purified water.

What Otrivine Adult Mucus Relief Menthol 0.1% w/v Nasal Spray looks like and the contents of the pack

Otrivine Adult Mucus Relief Menthol 0.1% w/v Nasal Spray is a nasal metered-dose spray containing a white solution with menthol and eucalyptol odour, in a bottle with a pump designed to deliver the correct amount of product.
The content of the pack is 10 ml.

Marketing Authorisation Holder

GlaxoSmithKline Consumer Healthcare (Ireland) Limited,
12 Riverwalk, CityWest Business Campus, Dublin 24, Ireland.

Manufacturer

GlaxoSmithKline Consumer Healthcare GmbH & Co. KG
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