

Package leaflet: Information for the patient
Otrivine Sinusitis Relief 0.1% w/v Nasal Spray
Xylometazoline Hydrochloride

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without a prescription. However, you still need to use Otrivine Sinusitis Relief 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.
- You must contact a doctor if the symptoms worsen or do not improve after 7 days.
- If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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

1. What Otrivine Sinusitis Relief Spray is and what it is used for

Otrivine Sinusitis Relief 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 Sinusitis Relief 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. What you need to know before you use Otrivine Sinusitis Relief 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). Symptoms include: rash, swelling of the face and throat, difficulty breathing.
- If you are taking, or have taken in the last two weeks, drugs for depression known as Monoamine Oxidase Inhibitors (MAOIs)
- have an overactive thyroid gland (hyperthyroidism)
- have acute heart disease
- have undergone recent trans-nasal surgery (brain surgery where the operation was carried out through the nose or mouth)
- have narrow angle glaucoma (increased pressure in eyes)
- have chronic nasal inflammation with very dry nasal passages (rhinitis sicca or atrophic rhinitis).

Tell your doctor or pharmacist if any of the above apply.

Take special care with Otrivine Sinusitis Relief Spray

Before using the spray tell your doctor or pharmacist if you:

- have high blood pressure
- suffer from a heart disease (e.g. long QT syndrome)
- suffer from diabetes mellitus

- have an enlarged prostate gland (prostatic hypertrophy)
- are taking medicines for depression called tri or tetra-cyclic antidepressants (see Other medicines and Otrivine Sinusitis Relief Spray).
- have a benign tumour of the adrenal gland that produces high amounts of adrenaline and noradrenaline (phaeochromocytoma).

Like other products for the relief of blocked nose, this product can give rise to sleep disturbances, dizziness and tremor in very sensitive individuals. Consult your doctor if these symptoms have proven troublesome to you.

Keep away from the eyes and mouth.

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

Do not take decongestants for more than 7 days in a row. Prolonged or excessive use may cause the stuffiness in the nose to return or worsen.

Other medicines and Otrivine Sinusitis Relief Spray

Please tell your doctor or pharmacist before using this product if you are taking, have recently taken or might take any other medicines.

Do not take Otrivine Sinusitis Relief Spray with monoamine oxidase inhibitors (e.g. tranylcypromine, phenelzine and isocarboxazid) as this may result in a dangerously high increase in blood pressure (See Section 2 'Do not use...').

Taking Otrivine Sinusitis Relief Spray with some medicines may cause an increase in blood pressure and is not recommended. These include:

- Blood pressure tablets (e.g. beta blockers such as propranolol, metoprolol)
- Tricyclic and tetracyclic anti-depressants (e.g. amitriptyline, clomipramine, amoxapine, loxapine).

Pregnancy or breast-feeding

If you are pregnant or breast-feeding, consult your doctor before using Otrivine.

Driving and using machines

Otrivine has very little or no effect on your ability to drive or use machines. If you have blurred vision then do not drive or operate machines.

Important information about some of the ingredients of Otrivine Sinusitis Relief Spray

Otrivine Sinusitis Relief Spray contains benzalkonium chloride which may cause nasal irritation, difficulty with breathing and wheezing.

3. How to use Otrivine Sinusitis Relief Spray

Dosage:

For Adults and Children over 12 years of age:

1 spray in each nostril 3 times daily as needed. Do not exceed 3 applications daily into each nostril. The last dose can be applied before going to bed.



Administration:

1. Before using for the first time, prime the pump by actuating (depressing the pump) 4 times. Once primed, the pump will normally remain charged throughout regular daily treatment periods. Should the spray not be ejected during the full actuation, the pump will need to be reprimed by actuating 4 times. Be careful not to spray in the eyes.
2. Do not cut the nozzle. The metered dose spray is ready to prime before use.
3. Blow your nose gently.
4. Hold the bottle upright with thumb under base and nozzle between two fingers.
5. Lean forward slightly and insert the nozzle into a nostril.
6. Spray and breathe in gently through the nose at the same time.
7. Repeat with the other nostril.
8. 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, especially in children and the elderly.

If you use more Otrivine Sinusitis Relief Nasal Spray than you should or accidentally swallow it, consult your doctor or pharmacist immediately.

4. Possible side effects

Like all medicines, Otrivine Sinusitis Relief 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 and seek medical help immediately if you have any of the following.

- difficulty breathing or swallowing.
- Swelling of the face, lips, tongue or throat.
- Severe itching of the skin, with red rash or raised bumps.

Common side effects (may affect up to 1 in 10 people)

Dryness or irritation of the nasal mucosa, nausea, headache or local burning sensation.

Uncommon side effects (may affect up to 1 in 100 people)

Nosebleeds

Very rare side effects (may affect up to 1 in 10,000 people)

Allergic reaction (skin rash, itching), temporary or passing blurred vision, irregular or fast heartbeat.

Cardiovascular effects, for example, palpitations, may also occur especially if you have heart problems.

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

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 HPRAs Pharmacovigilance website: www.hpra.ie.

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

5. How to store Otrivine Sinusitis Relief Spray

Keep out of the sight and reach of children.

Do not use after the expiry date which is stated on the bottle after “EXP”. The expiry date refers to the last day of that month.

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. Contents of the pack and other information

What Otrivine Sinusitis Relief Spray contains

The **active** ingredient is xylometazoline hydrochloride (0.1% w/v, 1 mg/ml).

The **other** ingredients are Benzalkonium chloride, Disodium phosphate dodecahydrate (Sodium phosphate), Disodium edetate, Sodium dihydrogen phosphate dihydrate (sodium acid phosphate), Sodium chloride, Sorbitol liquid non-crystallising (E420), Hypromellose, Purified water.

What Otrivine Sinusitis Relief Spray looks like and the contents of the pack

Clear aqueous solution in a 10 ml bottle.

Marketing Authorisation Holder

Haleon Ireland Limited, Clocherane, Dungarvan, Co. Waterford, Ireland

Manufacturer

Haleon Germany GmbH, Barthstraße 4, 80339 München, Germany

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Xylometazoline Hydrochloride

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

In this leaflet:

7. What Otrivine Sinusitis Relief Spray is and what it is used for
8. What you need to know before you use Otrivine Sinusitis Relief Spray
9. How to use Otrivine Sinusitis Relief Spray
10. Possible side effects
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12. Contents of the pack and other information

4. What Otrivine Sinusitis Relief Spray is and what it is used for

Otrivine Sinusitis Relief 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 Sinusitis Relief 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.

5. What you need to know before you use Otrivine Sinusitis Relief 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). Symptoms include: rash, swelling of the face and throat, difficulty breathing.
- If you are taking, or have taken in the last two weeks, drugs for depression known as Monoamine Oxidase Inhibitors (MAOIs)
- have an overactive thyroid gland (hyperthyroidism)
- have acute heart disease
- have undergone recent trans-nasal surgery (brain surgery where the operation was carried out through the nose or mouth)
- have narrow angle glaucoma (increased pressure in eyes)
- have chronic nasal inflammation with very dry nasal passages (rhinitis sicca or atrophic rhinitis).

Tell your doctor or pharmacist if any of the above apply.

Take special care with Otrivine Sinusitis Relief Spray

Before using the spray tell your doctor or pharmacist if you:

- have high blood pressure
- suffer from a heart disease (e.g. long QT syndrome)
- suffer from diabetes mellitus

- have an enlarged prostate gland (prostatic hypertrophy)
- are taking medicines for depression called tri or tetra-cyclic antidepressants (see Other medicines and Otrivine Sinusitis Relief Spray).
- have a benign tumour of the adrenal gland that produces high amounts of adrenaline and noradrenaline (phaeochromocytoma).

Like other products for the relief of blocked nose, this product can give rise to sleep disturbances, dizziness and tremor in very sensitive individuals. Consult your doctor if these symptoms have proven troublesome to you.

Keep away from the eyes and mouth.

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

Do not take decongestants for more than 7 days in a row. Prolonged or excessive use may cause the stuffiness in the nose to return or worsen.

Other medicines and Otrivine Sinusitis Relief Spray

Please tell your doctor or pharmacist before using this product if you are taking, have recently taken or might take any other medicines.

Do not take Otrivine Sinusitis Relief Spray with monoamine oxidase inhibitors (e.g. tranylcypromine, phenelzine and isocarboxazid) as this may result in a dangerously high increase in blood pressure (See Section 2 'Do not use...').

Taking Otrivine Sinusitis Relief Spray with some medicines may cause an increase in blood pressure and is not recommended. These include:

- Blood pressure tablets (e.g. beta blockers such as propranolol, metoprolol)
- Tricyclic and tetracyclic anti-depressants (e.g. amitriptyline, clomipramine, amoxapine, loxapine).

Pregnancy or breast-feeding

If you are pregnant or breast-feeding, consult your doctor before using Otrivine.

Driving and using machines

Otrivine has very little or no effect on your ability to drive or use machines. If you have blurred vision then do not drive or operate machines.

Important information about some of the ingredients of Otrivine Sinusitis Relief Spray

Otrivine Sinusitis Relief Spray contains benzalkonium chloride which may cause nasal irritation, difficulty with breathing and wheezing.

6. How to use Otrivine Sinusitis Relief Spray

Before first use

Prime the pump by pumping 5 times. Once primed the pump will normally remain charged throughout regular daily treatment periods.

Dosage:

For Adults and Children over 12 years of age:

1 spray in each nostril 3 times daily as needed. Do not exceed 3 applications daily into each nostril. The last dose can be applied before going to bed.

Administration:

Remove cap.

Be careful not to spray in the eyes and mouth.

1. Clear the nose.
2. Hold the bottle with thumb on the actuation button.
3. For a no dripping effect, stay upright and insert the short nozzle into a nostril.
4. Press on the button to spray and breathe in gently through the nose at the same time. Repeat this procedure (steps 2 to 4) in the other nostril.
5. After each use, clean and dry the nozzle
6. Put the protective cap back on until an audible “click” is heard.



Should the spray not be ejected during the full actuation stroke, or if the product has not been used for longer than 7 days, the pump will need to be re-primed with 2 pumps.

If the full spray is not administered, the dose should not be repeated.

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

Do not exceed the recommended dosage, especially in children and the elderly

If you use more Otrivine Sinusitis Relief Nasal Spray than you should or accidentally swallow it, consult your doctor or pharmacist immediately.

7. Possible side effects

Like all medicines, Otrivine Sinusitis Relief 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 and seek medical help immediately if you have any of the following.

- difficulty breathing or swallowing.
- Swelling of the face, lips, tongue or throat.
- Severe itching of the skin, with red rash or raised bumps.

Common side effects (may affect up to 1 in 10 people)

Dryness or irritation of the nasal mucosa, nausea, headache or local burning sensation.

Uncommon side effects (may affect up to 1 in 100 people)

Nosebleeds

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Allergic reaction (skin rash, itching), temporary or passing blurred vision, irregular or fast heartbeat.

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Reporting of side effects

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You can also report side effects directly via HPRA Pharmacovigilance website: www.hpra.ie.

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

8. How to store Otrivine Sinusitis Relief Spray

Keep out of the sight and reach of children.

Do not use after the expiry date which is stated on the bottle after “EXP”. The expiry date refers to the last day of that month.

Do not store above 30 °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.

9. Contents of the pack and other information

What Otrivine Sinusitis Relief Spray contains

The **active** ingredient is xylometazoline hydrochloride (0.1% w/v, 1 mg/ml).

The **other** ingredients are Benzalkonium chloride, Disodium phosphate dodecahydrate (Sodium phosphate), Disodium edetate, Sodium dihydrogen phosphate dihydrate (sodium acid phosphate), Sodium chloride, Sorbitol liquid non-crystallising (E420), Hypromellose, Purified water.

What Otrivine Sinusitis Relief Spray looks like and the contents of the pack

Clear aqueous solution in a 10 ml bottle.

Marketing Authorisation Holder:

Haleon Ireland Limited, Clocherane, Dungarvan, Co. Waterford, Ireland

Manufacturer

Haleon Germany GmbH, Barthstraße 4, 80339 München, Germany

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