


145 mm

11.5


297 mm

PHARMA CODE REF. IS: 1809

72 mm



HALEON



Otrivin

Patient Information Leaflet (PIL)

Otrivin

Otrivin 0.1% (Each ml contains 1mg Xylometazoline Hydrochloride)

Otrivin 0.1% Metered-Dose Nasal Spray

Otrivin 0.1% Nasal Drops

Adult Nasal Drops

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

- Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- You must talk to your doctor if you do not feel better or if you feel worse.

In this leaflet:

- What Otrivin 0.1% is and what it is used for?
- How you need to know before you use Otrivin 0.1%?
- How to use Otrivin 0.1%?
- Possible side effects
- How to store Otrivin 0.1%
- Contents of the pack and other information

1. What Otrivin 0.1% is and what it is used for?

Otrivin Adult 0.1% is on application in the nose to give relief from:

- nasal congestion (blocked nose, including colds)
- perennial and allergic rhinitis (incurring inflammation of the nasal mucous membranes, including hay fever)
- rhinitis (all due to drainage of secretions in inflammation of the paranasal sinuses).

As an adjunct in sinusitis, to decrease the nasopharyngeal pressure.

To facilitate rhinotomy.

Otrivin Adult 0.1% 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 Otrivin 0.1%?

a. do not use Otrivin if:

- You are allergic to xylometazoline or any other ingredient of this medicine.
- You have undergone recent nasal surgery (brain surgery where the operation was carried out through the nose or mouth).
- You suffer from a heart disease.
- You have an overactive thyroid gland (hyperthyroidism).
- You suffer from diabetes.
- You have an enlarged prostate gland (prostatic hypertrophy).
- You have a benign tumour of the adrenal gland that produces high amounts of adrenaline and noradrenaline (phaeochromocytoma).
- You are being treated with some antidepressants known as monoamine oxidase inhibitors (MAOIs) or if you have used them within the previous 2 weeks.
- If any of the above applies, do not use Otrivin before talking to your doctor or pharmacist.
- Like other products for the relief of blocked nose, Otrivin may be used for the relief of sinusitis, rhinitis, hay fever, and in severe allergic reactions. Consult your doctor if you have taken or are taking MAOIs within the last 14 days.
- Do not exceed the recommended dosage, especially in children and in the elderly.
- Otrivin 0.1% should not be used for longer than 12 years of age.
- Do not use if you are pregnant or breastfeeding.

b. Taking other medicines with Otrivin:

- Talk to your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, you should not use Otrivin if you are taking:
- Certain medicines used for treatment of depression. These medicines are: Monoamine oxidase inhibitors (MAOI), or NGF use Otrivin if you are taking or have been taking MAOIs within the last 14 days.
- Tricyclic and imipramine antidepressants.
- Potentially hypertensive medicine or medicines for Parkinson's disease (levodopa).
- If you use any of the above medicines, consult a doctor before using Otrivin.

c. Pregnancy and breast-feeding

- Otrivin should not be used during pregnancy due to potential systemic vasoconstrictor effect.
- The use of Otrivin while breast feeding should only take place on the instructions of a doctor.
- There is no relevant data on the effect of Otrivin on fertility, and controlled studies in animals are not available. Since systemic exposure to xylometazoline is very low, effects on fertility are highly unlikely.
- Ask your doctor or pharmacist for advice before taking any medicine.

d. Driving and using machines

- It is used within the recommended dosage, there is no or negligible influence on the ability to drive and use machines.
- It is used over a longer term or at a higher dose, the potential for systemic activity with cardiovascular effects cannot be excluded.

h. How to use Otrivin?

- Otrivin Nasal Drops and Metered Dose Nasal Sprays are for Nasal administration ONLY.
- Do not get Otrivin in the mouth or eyes.
- Do not exceed the recommended dosage, especially in children and the elderly.
- It is recommended to make the last application shortly before going to bed.
- Otrivin should not be used for longer than 1 week since prolonged use can lead to damage to mucosa (rhinitis medicamentosa).
- Always use Otrivin exactly as recommended below. You should check with your doctor or pharmacist if you are not sure.

Product

Otrivin 0.1% Nasal Drops

2-3 drops of 0.1% solution in each nostril. Repeat as needed, generally 3 times daily per day are sufficient.

Otrivin 0.1% Metered Dose Nasal Spray

1 spray puff from 0.1% needed spray in each nostril. Repeat as needed, generally 3 times daily per day are sufficient.

If you forget to use Otrivin:

- Do not take a double dose to make up for a forgotten one.

Overdose:


Excessive administration of topical xylometazoline hydrochloride or accidental ingestion may cause severe dizziness, perspiration, severely lowered body temperature, headache, bradycardia, hypertension, respiratory depression, coma and convulsions. Hypertension may be followed by hypotension. Small children are more sensitive to toxicity than adults. Appropriate supportive measures should be initiated in all individuals suspected of an overdose, and urgent symptomatic treatment under medical supervision is indicated when warranted. This would include observation of the individual for several hours. In the event of a severe overdose with cardiac arrest, resuscitation should be continued for at least 1 hour.

• Instructions for using Otrivin Drops:

- Clear your nose gently.
- Before using, practice using the dropper to develop good dosage control.
- Tilt your head back so far as is comfortable or, if lying on a bed, hang the head over the side.
- Without touching the dropper to the nose, apply the drops into each nostril and keep the head tilted back for a short time to allow the drops to spread throughout the nose.
- If the drop completely misses your nose, administer the drop again.
- If any part of the drop gets into your nose, do not administer the drop again.
- Repeat with the other nostril.
- Clean and dry the dropper before replacing it back into the bottle right after use.
- To avoid possible spread of infection, the bottle should only be used by one person.

• Instruction for using Otrivin Metered Dose Nasal Spray:

- Do not cut the nozzle. The metered dose spray is ready to prime before use.



- Clear your nose (your child's nose gently).
- Remove protective cap.
- Before using for the first time, prime the pump by actuating 4 times. Once primed, the pump will normally remain charged throughout regular daily treatment periods. If the spray is not 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 reprimed with 4 actuations. Be very careful not to spray in the eyes or mouth.
- Hold the bottle sprayer with thumb under base and nozzle between two fingers.
- Lean forward slightly and insert the nozzle into the nostril.
- Spray and breathe in gently through the nose at the same time.
- Repeat with the other nostril.
- Clean and dry the nozzle before replacing back the cap right after use.
- To avoid possible spread of infection, the spray should only be used by one person.
- If any of the side effects are serious or if you notice any other side effects not listed in this leaflet, please tell your doctor or pharmacist.

4. Possible Side Effects:

Use of medicines, Otrivin can cause side effects, although not everybody gets them. STOP using Otrivin and seek medical help immediately if you have any of the following which may be a sign of an allergic reaction:

- Difficulty breathing or swallowing.
- Swelling of the face, lips, tongue or throat.
- Severe itching of the skin, with or without red rash or raised bumps.
- Irregular heartbeat.

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

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

Very rare side effects (may affect less than 1 in every 10,000 people):

Allergic reactions (skin rash, itching, blurred vision, irregular or fast heartbeat, drug-induced swelling of the nasal mucosa (rhinitis medicamentosa)).

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

5. How to Store Otrivin?

The medicinal product must not be used beyond the date which appears after the letters <EXP> on the container. The expiry date refers to the last day of that month. This date applies even if the packaging is opened.

Don't store above 30°C. Protect from heat.

Medicinal products should be kept out of the reach and sight of children. *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 Otrivin contains:
- Active Ingredient

Otrivin 0.1% (Each ml contains 1mg of Xylometazoline hydrochloride)

Otrivin 0.1% Metered Dose Nasal Spray:

Each metered dose spray delivers 0.14 ml of Xylometazoline hydrochloride.

Otrivin 0.1% Nasal Drops:

Each drop delivers 0.025 mg of Xylometazoline hydrochloride.

- The products contain the following ingredients: Butylparaben, Chlorbutol (a preservative), Sodium dodecyl sulphate phosphate dihydrate, Sodium phosphate dodecylate, Sodium acetate, Sodium chloride, Sodium 70% (Non crystallizing), Methylhydroxypropylcellulose 4000 mPa.s, Purified water.

What Otrivin looks like and the content of the pack?

Otrivin 0.1% Metered-Dose Nasal Spray:

- Clear solution in a bottle with a pump delivering just the right amount of product.
- The content of the pack is 30 ml.

Otrivin 0.1% Metered Dose Nasal Spray

- High density polyethylene bottle mounted with a metered-dose pump (materials in contact with the solution: low density polyethylene, high density polyethylene, polyethylene / butyl, stainless steel and a polypropylene nozzle with a protective cap).
- Clear solution in a bottle with a pipette.
- The content of the pack is 30 ml.

Otrivin 0.1% Nasal Drops:

- Clear solution in a bottle with a pipette.
- The content of the pack is 30 ml.

Manufactured by Haléon CH SARL Nyon, Switzerland.

MAH: Helikon Schwiag AG, Switzerland.

November 2007-PRON v 1.0

Leaflet last revision date: October 2023

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To report any side effect(s):

Kliniken of Saudi Arabia

- National Pharmaceutical centres (NPC)
- For: +966-11-2025-760
- Reporting hotline: 19999
- Email: npc-drug@hga.gov.sa
- Website: <https://nrc.hga.gov.sa>
- Haléon Saudi Arabia - Head Office, Jeddah**
- Tel: +966-2-501-5444
- Mobile: +966-53-553-3647
- Email: marketing@halcon.com
- P.O. Box 48034, Jeddah 21572, Saudi Arabia

For any information about this medicinal product, please contact:

Haléon Saudi Arabia - Head Office, Jeddah

- Tel: +966-2-501-5444
- Email: marketing@halcon.com
- P.O. Box

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TECHNICAL INFORMATION

62000000123456

SITE COMPONENT NUMBER

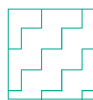
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Use the 14-digit site component number



PHARMACODE AREA

TEXT & GRAPHICS FREE
STARTING POINT ON THE LEFT

BAR HEIGHT : 7.0 mm
CODE LENGTH : VARIABLE



TEXT AND GRAPHIC FREE AREA

Blank or Technical Area

COPY AREA

Text and Graphic Area

CUT

Legacy number = P07

STUDIO REFERENCE No.	N/A
SUPPLIER REFERENCE No.	N/A
DRAWING OWNER (SITE)	NYON

LEAFLET 145 X 297 MM

DRAWING No.	AWDRG-1016	V1
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SCALE: 1:1 ALL DIMS. IN MILLIMETRES	GENERAL DRAWING TOLERANCE UNLESS STATED OTHERWISE N/A
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V2

03 - JUN - 2025

Artwork Information Panel


HALEON

Non Production Artwork

Production Artwork ☒

Component No: 62000000218860	AWP No: 8064202
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Total Number of Colours including Varnish & Foils: 1

						Nylon <small>(Printed Nylon American Network will have N/A in this field)</small>	
						Approving Market: Saudi Arabia-SAU	
1. Black		2.	3.	4.	5.	6.	Technical Drawing No: (P07) AWDRG-1016 v1
							Material Spec No: P07 <small>(Printed Nylon American Network will have N/A in this field)</small>
							Body Text Size: 4.5pt Smallest Text Size: 4.5pt <small>(Note: For North American Network, see Regulatory Spec link for this information)</small>
7.		8.	9.	10.	11.	12.	Electronic Verification Code: 1809
Total Special Finishes: 0							Printer and User notes:

Studio Location: SGS

AIP_CHAMPS_2023_HALEON

145 mm

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

72 mm

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297 mm

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	<p><u>TEXT AND GRAPHIC FREE AREA</u> Blank or Technical Area</p>
	<p><u>COPY AREA</u> Text and Graphic Area</p>
	<p><u>CUT</u></p>
<p>Legacy number = P07</p>	
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<div>DRAWING No.</div>	<div>AWDRG-1016</div>
<div>V1</div>	
<p>COPYRIGHT AND DESIGN RIGHT IS THE PROPERTY OF HALEON</p>	
<p>SCALE: 1:1 ALL DIMS. IN MILLIMETRES</p>	<p>GENERAL DRAWING TOLERANCE UNLESS STATED OTHERWISE N/A</p>

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Total Number of Colours including Varnish & Foils: 1		Manufacturing Site: Nyon <small>(Note: North American Artwork will have N/A in this field)</small> Approving Market: Saudi Arabia-SAU				
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1. Black	2.	3.	4.	5.	6.	
						Electronic Verification Code: 1809
Total Special Finishes: 0						Printer and User notes:
Studio Location: SGS						