

145 mm


11.5 mm

Recto

Pharma code 1129

297 mm

72 mm



11.5 mm

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

Nasal drops, nasal spray nebuliser, nasal gel, metered dose nasal spray
Local vasoconstrictor for nasal decongestion

Composition
Active ingredient: xylometazoline hydrochloride.
Pharmaceutical forms: Nasal drops: 0.05% and 0.1%.
Nebuliser: 0.1% solution. Nasal gel: 0.1%. Metered dose nasal spray: 0.05% and 0.1% aqueous solution.
Excipients: Conserv. (benzalkonium chloride). Aromatic agents in the gel.
One spray puff corresponds to 0.14 mg (0.1% solution) and 0.035 mg (0.05% solution) of xylometazoline hydrochloride.
Other Ingredients for Nasal drops (0.05% and 0.1%) and Metered dose nasal spray (0.05% and 0.1%) aqueous solution : sodium dihydrogen phosphate dihydrate, disodium phosphate dodecahydrate, disodium edetate, benzalkonium chloride (as solution) as a preservative, sorbitol, hypromellose, sodium chloride.

Properties/Effects
Xylometazoline is an arylalkyl imidazoline. Otrivin must be administered into the nasal cavities, where it exerts a vaso-constrictive effect leading to decongestion of the nasal and pharyngeal mucosa. Otrivin thus makes it easier to breathe through the nose when suffering from a cold or a chill. Otrivin contains ingredients which should prevent the drying of nasal mucous membrane.
The effect of Otrivin is felt within a few minutes and lasts for up to 10 hours. Even when the mucous membranes are sensitive, Otrivin is well tolerated and does not impair the function of the ciliated epithelium. Otrivin gel is particularly designed to ease respiration through the nose at night. The excipient contained in the gel prevents the nasal mucous membrane from drying out: it is thus specially adapted to the treatment of rhinitis with scab formation.

Pharmacokinetics
Following local application, the plasma concentration of the active ingredient of Otrivin is too low to be detected with current analytical methods.

Indications/Possible uses
Relief of nasal congestion due to colds, hay fever or other allergic rhinitis, sinusitis. To aid drainage of secretions in sinus conditions. In otitis media, as an adjuvant to decongest the nasopharyngeal mucosa. To facilitate rhinoscopy.

Dosage/Directions for use
Nasal drops 0.05% for small children from 1 to 11 years and only under adult supervision.
Do not use in children less than 1 year:
Each drop of Otrivin 0.05 % (per 1 ml) delivers 0.0125 mg of xylometazoline hydrochloride.
Children 1 to 5 years; with adult supervision – 1 to 2 drops into each nostril, once or twice daily (every 8 to 10 hours) are generally sufficient. Do not exceed 3 applications daily into each nostril.
Children 6 to 11 years; with adult supervision – 2 to 4 drops into each nostril, 2 to 3 times daily as needed. Do not exceed 3 applications daily into each nostril.
Nasal drops 0.1% for adults and children over 12 years of age only:
Each drop of Otrivin 0.1 % (per 1 ml) delivers 0.025 mg of xylometazoline hydrochloride.
2–4 drops of 0.1% solution into each nostril per application; 3 applications a day are usually sufficient. It is recommended to make the last application shortly before retiring to bed. Otrivin 0.1% should not be used in children aged less than 12 years.



Use of the nasal drops:
Clear the nose. Tilt the head back as far as is comfortable or, if lying on a bed, hang the head over the side. 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. 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.

Nebuliser 0.1% for adults and children over 12 years of age only:
1 to 2 sprays into each nostril, up to 3 times daily as needed. Do not exceed 3 applications daily into each nostril.
Use of the nebuliser:
To produce a fine spray the nebuliser should be held upright with the nozzle pointing upward. Be careful not to spray in the eyes. Clear the nose. Lean forward slightly and insert the nozzle into a nostril. Squeeze the bottle once and breathe in gently at the same time. Remove the nozzle before releasing the pressure on the bottle. 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.

Metered dose nasal spray 0.05% for small children from 1 to 11 years and only under adult supervision.
Do not use in children less than 1 year:
Children 1 to 5 years; with adult supervision – 1 spray into each nostril, once or twice daily (every 8 to 10 hours) are generally sufficient. Do not exceed 3 applications daily into each nostril.
Children 6 to 11 years; with adult supervision – 1 to 2 sprays into each nostril, 2 to 3 times daily as needed. Do not exceed 3 applications daily into each nostril.
Metered dose nasal spray 0.1% for adults and children over 12 years of age:
One spray into each nostril up to 3 times daily as needed. Do not exceed 3 applications daily into each nostril. It is recommended to make the last application shortly before retiring to bed.

The metered dose nasal spray permits accuracy of dosage and ensures that the solution is well distributed over the surface of the nasal mucosa. It precludes the possibility of unintentional overdose. Each metered dose nasal spray of Otrivin 0.05 % delivers 0.07 ml per actuation (0.035 mg of xylometazoline hydrochloride). Each metered dose nasal spray of Otrivin 0.1 % delivers 0.14 ml per actuation (0.14 mg of xylometazoline hydrochloride).

Use of the metered dose nasal spray:
Remove the protective cap. Before using for the first time, pump several times (fig. 1) until an even spray mist emerges. For subsequent applications, the metered dose nasal spray will then be ready for instant use. Insert the nozzle of the metered dose nasal spray into the nostril and press once firmly on the spray head (fig. 2), then withdraw the nozzle before releasing the pressure. Optimal distribution of the spray is achieved by inhaling gently through the nose during the spraying process. Replace the protective cap after each use.

Nasal gel for adults and children over 12 years of age only:
Apply a small quantity of gel as deeply as possible into each nostril 3-4 times a day. The last application should normally be made shortly before bedtime.

9 mm

127 mm

9 mm

11.5 mm

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		Diadeis Suisse SA – ADO – DO-19-E3646 – 20.01.2020 – F27			
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				Leading: 8.5 pts	
				Horizontal Scale: 100%	
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Verso

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9 mm

127 mm

9 mm

For all dosage forms:
Do not give a double dose to make up for a forgotten one. Otrivin should not be used for more than 10 consecutive days. The recommended dose should not be exceeded especially in children and the elderly.

Restrictions on use
Contraindications

- Hypersensitivity reaction to xylometazoline or any other ingredient of the preparation,
- After trans-sphenoidal hypophysectomy or surgery exposing the dura mater,
- Narrow-angle glaucoma, and
- Rhinitis sicca or atrophic rhinitis.
- Otrivin 0.025% should not be used in infants aged less than 1 year without medical advice.
- Otrivin 0.05% is contraindicated in children aged less than 1 year old.
- Otrivin 0.1% is contraindicated in children aged less than 12 years.

Precautions
Xylometazoline, like other sympathomimetic agents, should be used with caution in patients showing a strong reaction to adrenergic substances, as manifested by signs of insomnia, dizziness, tremor, cardiac arrhythmias or elevated blood pressure.
Otrivin should be used with caution in patients with: hypertension, cardiovascular disease, hyperthyroidism, diabetes mellitus, phaeochromocytoma, prostatic hypertrophy, monoamine oxidase inhibitors (MAOI) treatment or who have received them in the last two weeks (see Interactions).
Like other topical vasoconstrictors:
Otrivin 0.025% should not be used for more than seven consecutive days; prolonged or excessive use may cause rebound congestion. Otrivin 0.05% and 0.1% should not be used for more than ten consecutive days; prolonged or excessive use may cause rebound congestion and/or atrophy of the nasal mucosa.
Keep out of the sight and reach of children.

Paediatric population:
Otrivin 0.05% is contraindicated in children aged less than 1 year old. It should be used in children aged 1 to 11 years old only under adult supervision.
Otrivin 0.1% should not be used in children below 12 years of age.

Pregnancy, breast feeding
Considering its vasoconstrictive properties, as a precaution, Otrivin should be avoided during pregnancy. It should be used while breast feeding only if prescribed by a doctor. Studies in women or in animals are not available. Consequently, the medicine should be administered only if the potential benefit justifies the potential risk to the foetus.
Fertility: There are no adequate data for the effects of Otrivin on fertility and no animal studies are available. As the systemic exposure to xylometazoline hydrochloride is very low, effects on fertility are therefore very unlikely.

Effect on the ability to drive and use machines
Otrivin has no or negligible influence on the ability to drive and use machines.

Undesirable side effects
Common (may affect up to 1 in 10 people)
Nervous system disorders: Headache.
Respiratory, thoracic and mediastinal disorders: Nasal dryness, Nasal discomfort, Apnoea in young infants and newborns.
Gastrointestinal disorders: Nausea.
General disorders and administration site conditions: Application site burning.

Very Rare (may affect up to 1 in 10,000 people).
Immune system disorders: Hypersensitivity reaction (angioedema, rash, pruritus)
Eye disorders: Transient visual impairment.
Cardiac disorders: Heart rate irregular, Heart rate increased.

Interactions
If used as recommended, systemic effects are negligible. However, some systemic effects of Otrivin may be enhanced if tri- or tetracyclic antidepressants, MAOI or other products which may raise blood pressure are taken at the same time, especially in case of overdose. Xylometazoline may potentiate the action of MAOI inhibitors and may induce hypertensive crisis. Xylometazoline is not recommended in patients who are taking or have taken MAOI's within the past 2 weeks.

Overdosage
i) 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.
ii) 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.

Further remarks
In cases of colds with scab formation, preference should be given to Otrivin nasal gel.

Storage
Medicines should be kept out of the reach of children. Protect from heat. Do not store above 30 °C. The product may be used up to the date <EXP> shown on the package.
Gel: Use within one month maximum after first opening the package.

Presentation
Nasal drops (0.05%): 10 ml.
Nasal drops (0.1%): 10 ml.
Nebuliser (0.1%): 10 ml.
Gel (0.1%): tube of 10 g.
Metered dose nasal spray (0.05%): 10 ml.
Metered dose nasal spray (0.1%): 10 ml.

Not all of these forms are available in all countries.

Registration Numbers:
Nasal drops (0.05%): 10 ml:
Kenya: 2197
Nigeria: 04-5350
Uganda: NDA/MAL/HDP/2875
Tanzania: TAN 00 4247 R01A NOV
Ethiopia: 3416/2307/REN/2016
Zambia: 242/013 (P)
Malawi: PMPB/PL260/4


Nasal drops (0.1%): 10 ml:
Kenya: 2195
Nigeria: 04-0026
Uganda: NDA/MAL/HDP/2471
Tanzania: TAN 00 4245 R01A NOV
Ethiopia: 3416/2310/REN/2016
Zambia: 242/014 (P)
Malawi: PMPB/PL260/5

Metered dose nasal spray (0.1%): 10 ml:
Ethiopia: NOV/SWI/050
Nigeria: B4-0350

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CH-1260 Nyon
Switzerland
for
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Print Process: N/A		Colour Standard Reference: N/A		Material Type: N/A	
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Total Colours & Varnishes: 1				Body Text Size: 8 pts	
Black				Smallest Text Size: 8 pts	
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