

Specification Nr	Format	Dimensions AxB	Cardboard grain	Pharma code	Scale	Owner	A. GEAY	
N-PN-P07 v1.1	Standard leaflets	145 x 297 mm	Parallel to « A »	CODE	1:1	Date	30 MARS 2020	




V6 24 - Feb - 2021				Artwork Information Panel			
D2A <input type="checkbox"/>		Non Production <input type="checkbox"/>		Production <input checked="" type="checkbox"/>		SGS No: 6157007	
CHAMPS No: PA000002394		Manufacturing Site: Nyon		Site Component No: 6200000055937		Approving Market: Hong Kong	
Site Change Control No: 200837246		Product Market Trade Name: OTRIVIN		Component Type: Leaflet		Technical Drawing No: P07 (v1.1)	
Material Spec No: NA		Print Process: Offset - Lithography		Pharma Code No: 850		Barcode No: NA	
Bar Width Reduction: NA		Formulation Code: NA		Body Text Size: 9pt		Leading: 9.5pt	
Micro Text: N		Horizontal Scale: 100%		Smallest Text Size: 8pt		Total Special Finishes: 0	
Studio Location: Shanghai							

297

145

72 mm +/- 0.0 mm

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Information intended for patients
Read this entire leaflet carefully before you start using Otrivin. It contains important information for you. Follow the instructions carefully to get the best results. Ask a doctor or a pharmacist if you need more information or advice. Keep this leaflet, you may need to read it again.

What is Otrivin and when is it used?
Otrivin is used for various types of colds. It is designed to be applied in the nostrils, where it exerts a vasoconstricting effect thereby decongesting the mucosa of the nose and the throat.

This effect allows patients with colds to breathe more easily through the nose. The action of Otrivin is felt within a few minutes and lasts for several hours. Otrivin contains ingredients which help prevent the nasal mucosa drying out.

When must Otrivin not be used?
If you have had surgery involving the head, it is up to your doctor to decide whether you can use Otrivin. This limitation also applies to all other vasoconstrictive products used in the nose. Otrivin must not be used in the case of very dry or chronically inflamed nasal mucosa (Rhinitis sicca or Rhinitis atrophicans) or in the case of acute (closed-angle) glaucoma. Patients who are allergic to any of the ingredients in Otrivin must not use this medicinal product.

What precautions must be taken when using Otrivin?
As with other medicinal products for colds, Otrivin can lead to sleep and vision problems or episodes of dizziness which are evidence of oversensitivity to the product.
Please consult your doctor if:

- these effects are very disruptive,
- your cold persists or gets worse or
- other problems appear.

Otrivin must be used with care in the case of hypertension, cardio-vascular disease, thyroid hyperactivity, enlarged prostate, phaeochromocytoma (a tumour of the adrenal glands) or diabetes (Diabetes mellitus).
You should not use Otrivin if you are currently taking a MAO inhibitor (a medicine against depression), or have taken one within the last 14 days.
You should also not use this medicine if you are taking certain anti-depressants (tricyclic or tetracyclic anti-depressants).
Otrivin must not be used for more than a week without medical advice because over a longer period of use, rebound congestion of the nasal mucosa (rhinitis medicamentosa) may appear. This would be very similar to the symptoms of a cold.
Please inform your doctor, pharmacist or chemist if:

- you suffer from another medical condition,
- you are allergic,
- you are already taking or using other medicinal products either internally or externally (even when as self-medication!).

How to store Otrivin:
Keep all medicines out of the reach and sight of children.

Can Otrivin be used during pregnancy or when breast-feeding?
Otrivin should not be used during pregnancy. If you are breast feeding, please consult your doctor before using Otrivin.

Overdosage:
If you have used more Otrivin than you should, inform your doctor immediately. Poisoning can occur through significant overdose or through accidental ingestion of the medicine.

What side-effects can Otrivin cause?
Stop using Otrivin and seek medical help immediately if you notice one of the following signs as it could be an allergic reaction:

- Difficulty breathing or swallowing,
- Swelling of face, lips, tongue and/or throat area,
- Strong itching with red rash and/or elevations on the skin,
- Irregular heartbeat.

Common side effects (in 1 to 10 out of every 100 patients):
Nasal dryness and irritation, nausea, headache and local burning sensation.
Very rare side effects (less than 1 out of every 10,000 patients):
Allergic reactions (skin rash, itching), temporarily blurred vision, irregular or accelerated heartbeat, drug-related nasal mucosal swelling (Rhinitis medicamentosa).
If you notice side-effects that are not mentioned in this leaflet, please tell your doctor or pharmacist.

Dosage and Administration:
Otrivin 0.05% is indicated in children aged 6 to 11 years old.
Children aged 6-11 years: 1 to 2 drops in each nostril, once or twice per day.

Otrivin should not be used for more than 7 consecutive days. If symptoms persist, consult your doctor. Prolonged or excessive use may cause stuffiness in the nose to return or worsen.

Do not exceed the recommended dosage.

Do not exceed 3 applications daily into each nostril. The last application of the day should preferably be shortly before going to bed.

What does Otrivin contain?
Otrivin nasal drops for children contain 0.05% of xylometazoline hydrochloride. The excipients include sodium dihydrogen phosphate dihydrate, disodium phosphate dodecahydrate, disodium edetate, benzalkonium chloride, sorbitol 70%, methylhydroxypropylcellulose 4000mPa-s, sodium chloride and purified water.


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Hong Kong

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PHARMA CODE REF: IS: 850

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D2A	<input type="checkbox"/> Non Production	<input type="checkbox"/> Production	SGS No: 6157007		CHAMPS No: PA000002394
Total Number of Colours including Varnish & Foils: 1			Manufacturing Site: Nyon		Site Component No: 6200000055937
1. Process Black			Approving Market: Hong Kong		Site Change Control No: 200837246
			Product Market Trade Name: OTRIVIN		Component Type: Leaflet
			Technical Drawing No: P07 (v1.1)		Material Spec No: NA
			Print Process: Offset - Lithography		Pharma Code No: 850
Total Special Finishes: 0			Barcode No: NA		Bar Width Reduction: NA
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