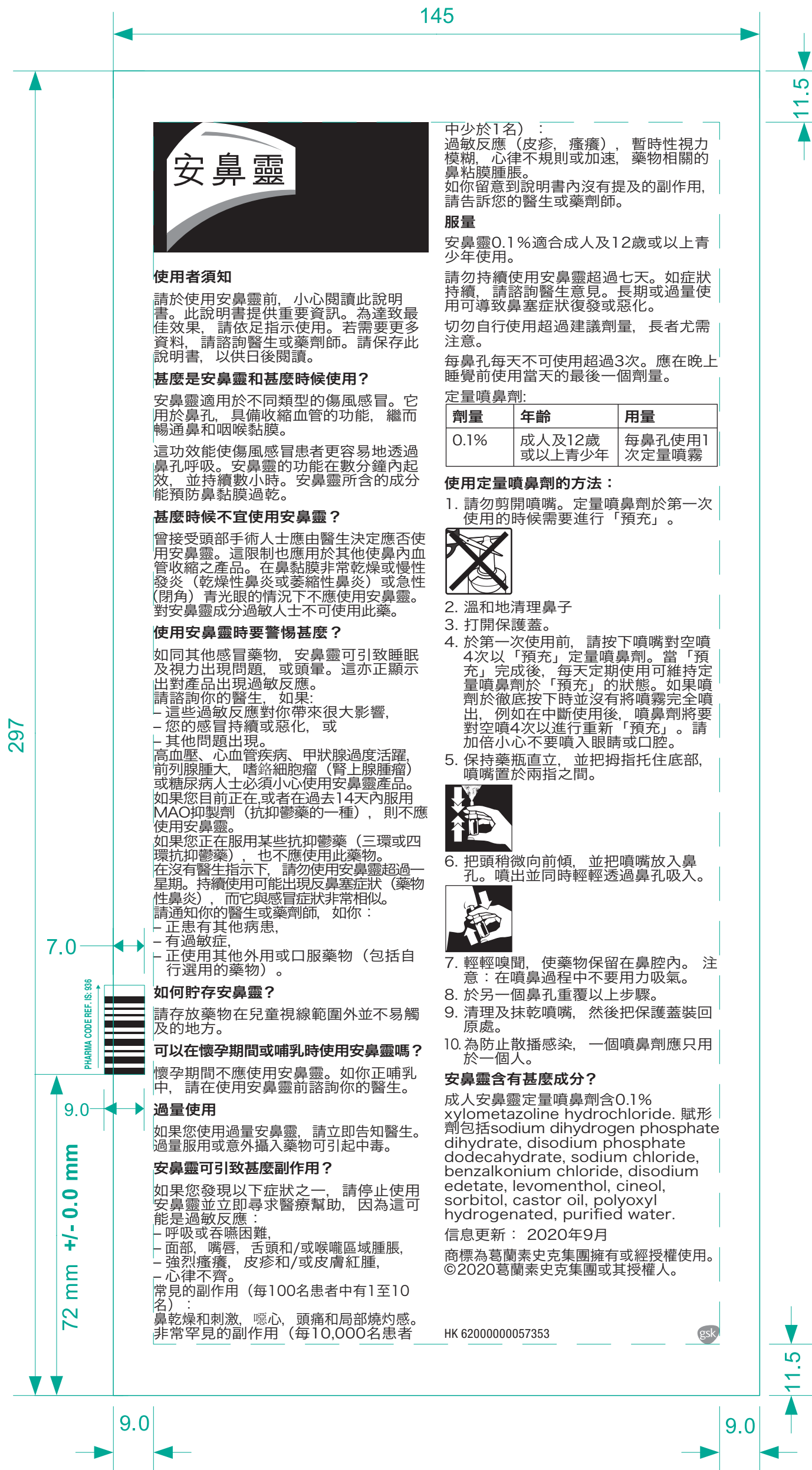


Specification Nr <b>N-PN-P07 v1.1</b>	Format <b>Standard leaflets</b>	Dimensions AxB <b>145 x 297 mm</b>	Cardboard grain <b>Parallel to « A »</b>	Pharma code <b>CODE</b>	Scale <b>1:1</b>	Owner <b>A. GEAY</b>	
						Date <b>30 MARS 2020</b>	



<b>V4</b> 24 - Feb - 2021		<b>Artwork Information Panel</b>	
D2A <input type="checkbox"/>	Non Production <input type="checkbox"/>	Production <input checked="" type="checkbox"/>	SGS No: 6197051
Total Number of Colours including Varnish & Foils: 1		Manufacturing Site: Nyon	CHAMPS No: PA0000003148
Process 1. Black		Approving Market: Hong Kong	Site Component No: 62000000057353
Total Special Finishes: 0		Product Market Trade Name: OTRIVIN	Site Change Control No: 200866184
		Technical Drawing No: P07 (v1.1)	Component Type: Leaflet
		Print Process: Offset - Lithography	Material Spec No: NA
		Barcode No: NA	Pharma Code No: 936
		Formulation Code: NA	Bar Width Reduction: NA
		Micro Text: N	Body Text Size: 9pt Leading: 2pt
Studio Location: Shanghai			Horizontal Scale: 110% Smallest Text Size: 8pt

145

11.5

72 mm +/- 0.0 mm

297


7.0

11.5

9.0

9.0

9.0



**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, pheochromocytoma (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 0.1% is indicated in adults and in adolescents aged 12 years and above.

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, especially in the elderly.

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

**Nasal metered-dose spray:**

Strength	Age	Posology
0.1%	Adults and adolescents aged 12 years and above.	1 spray into each nostril


**Method for using the metered-dose nasal spray:**

- Do not cut the nozzle. The metered dose spray is ready to prime before use.
- Gently clear your nose.
- 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 e.g. after a break from use, the pump will need to be reprimed with 4 actuations. Be very careful not to spray in the eyes or mouth.
- Hold bottle upright with thumb under base and nozzle between two fingers.
- Lean your head forward slightly and insert the nozzle into the nostril.  
Spray and breathe in gently through the nose at the same time.
- Sniff gently to allow the medication retaining in the nasal cavity. Caution: do not forcefully breathe in during the spray.
- 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.

**What does Otrivin contain?**  
Otrivin metered-dose nasal spray contains 0.1% of xylometazoline hydrochloride. The excipients include sodium dihydrogen phosphate dihydrate, disodium phosphate dodecahydrate, sodium chloride, benzalkonium chloride, disodium edetate, levomenthol, cineol, sorbitol, castor oil, polyoxyl hydrogenated, purified water.

Last revised: September, 2020

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24 - Feb - 2021							
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1. Process Black				Approving Market: Hong Kong		Site Change Control No: 200866184	
				Product Market Trade Name: OTRIVIN		Component Type: Leaflet	
				Technical Drawing No: P07 (v1.1)		Material Spec No: NA	
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