1. Name of the medicinal product

XYLOMETAZOLINE HYDROCHLORIDE NASAL SOLUTION USP 0.1 % W/V

2. Qualitative and quantitative composition

ACTIVE INGREDIENTS				
APPROVED NAME	SPECIFICATION OR REFERENCE TEXT	QTY/ 10 ML		% OVERAGES
		QTY. / 10 ML	%W/W/ 10 ML	
XYLOMETHAZOLINE HCL*	USP	0.010 MG	0.10%	5.00%
INACTIVE INGREDIENTS				
APPROVED NAME	SPECIFICATION OR REFERENCE TEXT	QTY/ 10 ML		REASON FOR INCLUSION
		QTY. / 10 ML	%W/W/10 ML	
SODIUM CHLORIDE	BP	0.077 MG	0.77%	ISOTONIC
BENZALKONIUM CHLORIDE	USP	0.002MG	0.02%	PRESERVATIVE
DISODIUM HYDROGEN PHOSPHATE	BP	0.002MG	0.02%	BUFFERING AGENT
DEMINERAL WATER	INHOUSE	10.0 ML	100%	VEHICLE

*5.0% Overages are added on label claim.

3. Pharmaceutical form

Nasal solution

4. Clinical particulars

4.1 Therapeutic indications

As a nasal decongestant for relief of the symptoms of acute rhinitis in allergic or upper respiratory tract infections, including the common cold or influenza. Relief of sinusitis.

4.2 Posology and method of administration

Adults (including the elderly) and adolescents over 12 years of age:
Narisol Adult should not be used for more than seven consecutive days. The recommended dose should not be exceeded.
Adults (including the elderly) and adolescents over 12 years of age: 2 to 4 drops 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.
Paediatric population:
Narisol Adult Nasal Drops should not be used in children aged less than 12 years.

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Route of administration: Nasal use.
1. Blow your nose gently.
2. Before using, practice using the dropper to develop good dosage control.
3. Tilt your head back as far as is comfortable or, if lying on a bed, hang the head over the side.
4. Without touching your nose with the dropper, 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.
5. If the drop completely misses your nose, administer the drop again.
6. If any part of the drop gets into your nose, do not administer the drop again.
7. Repeat with the other nostril.
8. Clean and dry the dropper before replacing it back into the bottle right after use.

4.3 Contraindications

- Hypersensitivity to xylometazoline or to any of the excipients.
- Narisol Adult should not be used in patients with trans-sphenoidal hypophysectomy or surgery exposing the dura mater.
- Patients with acute coronary disease, hyperthyroidism or narrow angle glaucoma.
- Use in patients who are receiving monoamine oxidase inhibitors, or within 14 days of stopping such treatments.
- Rhinitis sicca and Atrophic rhinitis.

4.4 Special warnings and precautions for use

Narisol Adult should be used with caution in patients with:
- Hypertension, cardiovascular disease
- Diabetes mellitus, phaeochromocytoma, prostatic hypertrophy
- Like other topical vasoconstrictors, Narisol Adult should not be used for more than seven consecutive days: prolonged or excessive use may cause rebound congestion and/or atrophy of the nasal mucosa.
- Narisol Adult, like other sympathomimetic agents, should be used only 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.
- Narisol Adult Nasal Drops contains benzalkonium chloride which may cause nasal irritation and bronchospasm.
- Do not exceed the recommended dose. The adult drops should not be used for infants or children under 12 years.
- For prevention of cross infection, it is recommended that each product package is used by one person only.

4.5 Interaction with other medicinal products and other forms of interaction

This product may alter the effects of some anti-hypertensives, such as beta-blockers, and of some anti-depressants, such as monoamine oxidase inhibitors (MAOIs), tricyclic and tetracyclic anti-depressants.

Monoamine oxidase inhibitors (MAO inhibitors): xylometazoline may potentiate the action of monoamine oxidase inhibitors and may induce hypertensive crisis. Xylometazoline is not recommended in patients who are taking or have taken MAOIs within the past two weeks.

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Tri- and tetra-cyclic antidepressants: concomitant use of tri- or tetra cyclic antidepressants and sympathomimetic preparations may result in an increased sympathomimetic effect of xylometazoline and is therefore not recommended.

4.6 Pregnancy and lactation

Pregnancy:
No foetal toxicity or fertility studies have been carried out in animals. In view of its potential systemic vasoconstrictor effect, Narisol Adult Nasal Drops should not be used during pregnancy.
Breastfeeding:
There is no evidence of any adverse effect on the breast-fed infant. However, it is not known if xylometazoline is excreted in breast milk, therefore caution should be exercised and Narisol Adult Nasal Drops should be used only under medical advice, whilst breast-feeding.

4.7 Effects on ability to drive and use machines

Narisol Adult has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Systemic cardiovascular effects have occurred, and this should be kept in mind when giving Narisol Adult to people with cardiovascular disease.
Adverse reactions are listed below, by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000) or very rare (<1/10,000). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.
Immune system disorders:
Very rare: Hypersensitivity reaction (angioedema, rash, pruritus)
Nervous system disorders:
Common: Headache
Eye disorders:
Very rare: Transient visual impairment
Cardiac Disorders:
Very rare: Heart rate irregular and heart rate increased
Respiratory, thoracic and mediastinal disorders:
Common: Nasal dryness or nasal discomfort, burning sensation
Gastrointestinal disorders:
Common: Nausea
General disorders and administration site conditions:
Common: Application site burning

4.9 Overdose

Overdose of oral or excessive administration of topical xylometazoline hydrochloride 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 may include observation of the individual for at least several hours.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: decongestants for topical use, sympathomimetics, plain. ATC Code: R01AA07.
Mechanism of action and pharmacodynamic effects:
Narisol Adult Nasal Drops is a sympathomimetic agent with marked alpha-adrenergic activity, and is intended for use on the nose.
It constricts the nasal blood vessels, thereby decongesting the mucosa of the nose and neighbouring regions of the pharynx. It also reduces associated symptoms of mucus hypersecretion and facilitates drainage of blocked secretions. This enables patients suffering from colds to breathe more easily through the nose.
The effect of Narisol Adult begins within a few minutes and lasts for up to 10 hours. The effect of Narisol Adult Nasal Drops is generally well tolerated and does not impair the function of ciliated epithelium.

5.2 Pharmacokinetic properties

Plasma concentrations of xylometazoline in man after local nasal application of the product are very low and close to the limit of detection.
Systemic absorption may occur following nasal application of xylometazoline hydrochloride solutions. It is not used systemically.

5.3 Preclinical safety data

Xylometazoline has no mutagenic effect. No teratogenic effects were known in a study were xylometazoline was given simultaneously in mice and rats.

6. Pharmaceutical particulars

6.1 List of Excipients

- Sodium chloride
- Benzalkonium chloride
- Disodium hydrogen phosphate
- Demineral water

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months

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6.4 Special precautions for storage

Store in a dry place at a temperature below 30°C.

6.5 Nature and contents of container

10 ML HDPE Dropper bottle, packed in printed and laminated carton.

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing authorisation holder

West Coast Pharmaceutical Works Ltd, Ahmedabad

8. Marketing authorisation number(s)

Not applicable.

9. Date of first authorisation/renewal of the authorisation

Not applicable.

10. Date of revision of the text

April, 2016