1. Name of the medicinal product

Xylometazoline Hydrochloride Nasal Solutioin USP 0.05%W/V

2. Qualitative and quantitative composition

ACTIVE INGREDIENTS				
APPROVED NAME	SPECIFICATION OR REFERENCE TEXT	QTY/ 10 ML		% OVERAGES
		MG/10 ML	%W/W/10 ML	
XYLOMETAZOLINE HCL*	USP	0.00525 GM 0.0050 GM	0.0525%	5.00%
INACTIVE INGREDIENTS				
APPROVED NAME	SPECIFICATION OR REFERENCE TEXT	QTY/ 10ML		REASON FOR INCLUSION
		MG/10 ML	%W/W/10 ML	
SODIUM CHLORIDE	BP	0.083 GM	0.83%	STABILIZER
DISODIUM HYDROGEN PHOSPHATE	BP	0.0015 GM	0.015%	BUFFER
DEMINERAL WATER	INHOUSE	9.910 ML	99.10%	VEHICLE
BENZALKONIUM CHLORIDE	USP	0.0011 GM	0.010%	PRESERVATIVE

*5.0% Overages are added on label claim.

3. Pharmaceutical form

Nasal Solution

4. Clinical particulars

4.1 Therapeutic indications

For the relief of nasal congestion associated with the common cold, perennial and allergic rhinitis (including hay fever), sinusitis.

4.2 Posology and method of administration

Adults and elderly: Not applicable.
Narisol Paediatric Nasal Solutioin are contraindicated in children under 6 years of age.
Children between 6 and 12 years (all indications):
1 or 2 drops, in each nostril 1 or 2 times daily.
Not to be used for more than 5 days without the advice of a doctor. Parents or carers should seek medical attention if the child's condition deteriorates during treatment.
Not more than 2 doses should be given in any 24 hours.
Route of administration: Nasal use

- Do not exceed the stated dose

WEST-COAST Pharmaceutical Works Ltd.

WEST-COAST PHARMACEUTICAL WORKS LTD AHMEDABAD

- Keep out of the reach and sight of children.

4.3 Contraindications

- Known hypersensitivity to Narisol Paediatric or any of the excipients
- Concomitant use of other sympathomimetic decongestants
- Cardiovascular disease including hypertension
- Diabetes mellitus
- Phaeochromocytoma
- Hyperthyroidism
- Closed angle glaucoma
- Monoamine oxidase inhibitors (MAOIs, or within 14 days of stopping treatment)
- Beta-blockers
- Inflammation of the skin and/or mucosa of the nasal vestibule
- Trans-sphenoidal hypophysectomy or nasal surgery exposing the dura mater
- Not to be used in children under the age of 6 years

4.4 Special warnings and precautions for use

Patients are advised not to take decongestants for more than five consecutive days. Narisol Paediatric, like other preparations belonging to the same class of active substances, should be used only with caution in patients showing a strong reaction to sympathomimetic agents as evidenced by signs of insomnia, dizziness etc.

- Do not exceed the stated dose
- Do not take with any other cough and cold medicine.
- Do not use continuously for more than five consecutive days. If symptoms persist consult your doctor
- If your child is receiving medication or is under a doctor's care, consult him before giving Narisol Paediatric
- Each Narisol Paediatric pack should be used by one person only to prevent any cross infection
- For reasons of hygiene do not use this bottle for more than 28 days after first opening it.
- Some patients who have sensitive nasal passages may feel some local discomfort when applying Nasal Solutioin.
- Other side effects such as palpitations, nausea and headache are very rare.
- Occasionally small children may show restlessness or sleep disturbance when Narisol Paediatric is used. If this occurs Narisol Paediatric should be stopped.
- Keep medicines out of reach and sight of children.
- Expectant mothers should consult their doctors before using Narisol Paediatric for themselves.

4.5 Interaction with other medicinal products and other forms of interaction

As for all sympathomimetics, a reinforcement of the systemic effects of Xylometazoline by concomitant use of monoamine oxidase inhibitors, tricyclic or tetracyclic antidepressants, cannot be excluded, especially in case of overdose.

WEST-COAST
Pharmaceutical Works Ltd.

WEST-COAST PHARMACEUTICAL WORKS LTD AHMEDABAD

4.6 Pregnancy and lactation

Narisol Paediatric nasal solution is only for paediatric use.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

The following side effects have occasionally been encountered: A burning sensation in the nose and throat, local irritation, nausea, headache, and dryness of the nasal mucosa.
Systemic cardiovascular effects have occurred, and this should be kept in mind when giving Narisol Paediatric to people with cardiovascular disease. In isolated cases, systemic allergic reactions and transient visual disturbances.

- Local effects – irritation and dryness
- Nausea
- Headache
- Rebound congestion (rhinitis medicamentosa) – especially with prolonged and/or heavy use
- Tolerance with diminished effect – especially with prolonged and/or heavy use
- Cardiovascular effects (as with oral agents) particularly with prolonged and/or excessive use
- CNS effects (as with oral agents) particularly with prolonged and/or excessive use

4.9 Overdose

In rare instances of accidental poisoning in children, the clinical picture has been marked chiefly by signs such as acceleration and irregularity of the pulse, elevated blood pressure and sometimes consciousness clouding.
There is no specific treatment. Appropriate supportive measures should be initiated.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Narisol Paediatric Nasal Solutioin is a sympathomimetic agent with marked alpha-adrenergic activity, and is intended for use in the nose. It constricts the nasal blood vessels, thereby decongesting the mucosa of the nose and neighbouring regions of the pharynx. This enables patients suffering from colds to breathe more easily through the nose. The effect of Narisol Paediatric Nasal Solutioin begins within a few minutes and lasts for up to 10 hours. Narisol Paediatric Nasal Solutioin is generally well tolerated and does not impair the function of ciliated epithelium.

5.2 Pharmacokinetic properties

Systemic absorption may occur following nasal application of Xylometazoline hydrochloride solutions. It is not used systemically.

WEST-COAST
Pharmaceutical Works Ltd.

WEST-COAST PHARMACEUTICAL WORKS LTD • AHMEDABAD

5.3 Preclinical safety data

There are no findings in the preclinical testing which are of relevance to the prescriber.

6. Pharmaceutical particulars

6.1 List of Excipients

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

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months

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

November, 2015

WEST COAST PHARMACEUTICAL WORKS LTD AHMEDABAD

WEST-COAST
Pharmaceutical Works Ltd.