1 NAME OF THE MEDICINAL PRODUCT

Tillomed Clear Nose Spray

Xylometazoline Decongestant Nasal Spray 0.1%w/v

NasoClear 0.1%w/v Decongestant Nasal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Xylometazoline Hydrochloride 0.1%w/v

Excipients with known effect

Benzalkonium chloride

Sodium

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Nasal spray.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The symptomatic relief of nasal congestion, perennial and allergic rhinitis (including hay fever) and sinusitis.

4.2 Posology and method of administration

Posology

By intranasal administration using nasal spray

Adults and children 12 years and above

1 spray into each nostril 1-3 times a day as required, for a maximum of 5 days.

Maximum daily use: no more than 3 doses should be given in any 24 hours.

Leave at least 8 hours between doses, unless otherwise advised by your doctor.

'Do not exceed the recommended dose.'
'Do not use for more than 5 consecutive days.'
'Continuous use of the product for more than 5 days can lead to an increased risk of side effects (see section 4.4).'
'Medical advice should be sought if symptoms of nasal congestion persist or worsen or do not improve after 5 days as alternative treatment may be required.'

Children under 12 years

Not suitable.

Method of administration

Application to the nasal passages.

The spray pump guarantees a good distribution of the solution on the surface of the mucosa. The dosing mechanism enables an accurate dosage and prevents an unintended overdose.

Remove the protective cap. Before first use, press the pump 5 times until an even spray is formed. The nasal spray is ready for use now. With repeated administration, the nasal spray will be ready for immediate use. If the spray has not been used for a maximum of 14 days (after first use), press the pump once to activate the nasal spray.

Avoid contact with eyes and mouth.

1. Blow your nose.
2. Hold the bottle upright and place your thumb at the bottom of the bottle and hold the nozzle between 2 fingers.
3. Tilt your head forward slightly and put the nozzle in a nostril.
4. Breathe in slowly and gently through your nose whilst pressing down the pump.
5. Clean and dry the nozzle before placing the protective cap.

The recommended dose should not be exceeded, especially in children and the elderly.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1

Patients with trans-sphenoidal hypophysectomy or surgery exposing the dura mater.

Narrow-angle glaucoma.

Rhinitis sicca or atrophic rhinitis.

Xylometazoline Decongestant Nasal Spray 0.1%w/v is contraindicated in children aged less than 12 years.

Use in people with phaeochromocytoma, prostatic hypertrophy or those receiving monoamine oxidase inhibitors (MAOI) treatment or who have received them in the last two weeks.

Do not take with other sympathomimetic decongestants.

4.4 Special warnings and precautions for use

Patients are advised not to take decongestants for more than seven consecutive days, prolonged or excessive use may cause rebound congestion and/or atrophy of the nasal mucosa.

Xylometazoline Decongestant Nasal Spray 0.1%w/v, 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, tremor, cardiac arrhythmias or elevated blood pressure.

Caution is recommended in patients with hypertension, cardiovascular disease, hyperthyroidism or diabetes mellitus.

Patients with long QT syndrome treated with xylometazoline may be at increased risk of serious ventricular arrhythmias.

This medicine is intended for short-term use only.

Repeated and/or prolonged administration can cause appreciable systemic exposure to the active substances and increase the risk of side effects.

Tachyphylaxis – a rapidly diminishing response to the drug after a few doses.

Using more of this product and/or using it for longer than recommended may also lead to reduced effect of a dose (due to repetitive drug exposure) and rebound congestion (see section 4.8).

Prolonged or excessive use may result in reactive hyperaemia, chronic swelling of the nasal mucosa known as rhinitis medicamentosa, and atrophy of the nasal mucosa. Increasing the dose and/or frequency of xylometazoline spray at onset of rebound congestion and/or rhinitis medicamentosa, will worsen the nasal congestion. Patients must stop treatment rather than increasing the dose or prolonging treatment. It is necessary to ensure that the treatment period does not exceed 5 days of continuous use. Alternative treatment may be required if nasal congestion persists beyond the recommended treatment period (see section 4.8).

Labelling (outer pack):

The label will state (to be displayed prominently on the front of the outer pack):

- For 5 days use only

The label will also state:

- Leave at least 8 hours between doses
- For short-term use only
- Do not use for more than 5 days in a row. Do not use more medicine than the label tells you to. If your symptoms worsen or you do not feel better after 5 days, stop treatment and seek medical advice.

<u>Information concerning excipients</u>

Xylometazoline Decongestant Nasal Spray 0.1%w/v contains benzalkonium chloride. This may cause irritation of the nasal mucosa.

This medicine contains less than 1mmol sodium (23mg) per dose, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

The concomitant use of xylometazoline with monoamine oxidase (MAO) inhibitors or tri- and tetra-cyclic antidepressants, may cause an increase in blood pressure due to the cardiovascular effects of these substances (see Contraindications).

4.6 Fertility, Pregnancy and lactation

No foetal toxicity or fertility studies on xylometazoline have been carried out in animals.

Pregnancy

In view of its potential systemic vasoconstrictor effect, it is advisable to take the precaution of not using xylometazoline during pregnancy.

Breastfeeding

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 Xylometazoline hydrochloride should be used only on the advice of a doctor whilst breast-feeding.

4.7 Effects on ability to drive and use machines

No effects on the ability to drive or to use machines would be anticipated.

4.8 Undesirable effects

The adverse effects listed below are classified by system organ class and frequency according to the following convention: 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), not known (frequency cannot be estimated from the available data).

MedDRA SOC	**Adverse reaction**	**Frequency**
Immune System Disorders	Hypersensitivity reaction (angioedema, rash,	Very rare

	pruritus)	
Nervous System Disorders	Headache	Common
Eye Disorders	Transient visual impairment	Very rare
Cardiac Disorders	Heart rare irregular Heart rate increased	Very Rare
Respiratory, thoracic and mediastinal disorders	Nasal Dryness Nasal Discomfort	Common
	Epistaxis	Uncommon
Gastrointestinal disorders	Nausea	Common
General disorders and administration site conditions	Application site burning	Common
	Tachyphylaxis (see section 4.4) Tolerance with diminished effect, especially with prolonged or heavy use (see section 4.4) Rebound congestion (see section 4.4) Rhinitis medicamentosa (see section 4.4)	Not known

Other side effects include:

- A burning sensation in the nose and throat

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms and Signs

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.

Treatment

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sympathomimetics, plain

ATC Code: R01AA

Xylometazoline 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 Xylometazoline Decongestant Nasal Spray begins within a few minutes and lasts for up to 10 hours. Xylometazoline Decongestant Nasal Spray 0.1% w/v is generally well tolerated and does not impair the function of ciliated epithelium.

In a double-blind, saline solution controlled study in patients with common cold, the decongestant effect of xylometazoline was significantly superior ($p<0.0001$) to saline solution based on rhinomanometry measurement at 1 hour after administration of the study drugs.

5.2 Pharmacokinetic properties

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

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride

Disodium edetate dihydrate

Sodium dihydrogen phosphate dihydrate

Disodium hydrogen phosphate dodecahydrate

Sodium chloride

Purified water

6.2 Incompatibilities

No major incompatibilities are known.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Do not store above 25°C.

Do not freeze

6.5 Nature and contents of container

Amber coloured, transparent glass bottle with a dosage mechanism of polyethylene or polypropylene, and polypropylene cap, content 10 ml.

Pack size: 1 x 10 ml bottle

6.6 Special precautions for disposal

No special requirements

Any unused product or waste material should be disposed of in accordance with local requirements

7 MARKETING AUTHORISATION HOLDER

Tillomed Laboratories Limited

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LU2 8DL

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 11311/0814

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19 November 2003/19 August 2010

10 DATE OF REVISION OF THE TEXT

05/11/2026