1 NAME OF THE MEDICINAL PRODUCT

Numark Nasal Decongestant Spray
Asda Decongestant 0.05% w/v Nasal Spray
Morrisons Nasal Decongestant Spray
Superdrug Nasal Decongestant Spray
Wilko Decongestant 0.05% w/v Nasal Spray
Tesco Health Blocked Nose Relief 0.05% w/v Nasal Spray
Galpharm Blocked Nose Relief 0.05% w/v Nasal Spray
Sainsbury's Healthcare Decongestant & hayfever 0.05% w/v Nasal Spray
Boots Decongestant 0.05% w/v Nasal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The nasal solution contains Oxymetazoline hydrochloride 0.05% w/v

Excipients with known effect:

The Nasal Decongestant Spray contains 0.040% w/v of Benzalkonium Chloride per dose.

The Nasal Decongestant Spray contains 0.001% w/v of Thiomersal per dose.

3 PHARMACEUTICAL FORM

This product is in the form of a solution for intranasal administration to human beings.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Oxymetazoline hydrochloride nasal spray is recommended for the relief of nasal congestion in such conditions as the common cold, catarrh and hayfever.

4.2 Posology and method of administration

Posology

Adults and Elderly

While holding upright the spray nozzle should be inserted into each nostril in turn and squeezed lightly twice while breathing in. The application may be repeated up to 2 times a day, or used at bedtime to give relief through the night.

Children

Do not give to children under 12 years of age.

Oxymetazoline hydrochloride 0.05% Nasal Spray should not be used for more than 7 consecutive days.

Method of administration

For nasal use.
The recommended daily dosage or the specified number of doses should not be exceeded (see section 4.4)

4.3 Contraindications

Hypersensitivity to oxymetazoline or to any of the excipient listed in section 6.1.

Patients suffering from phaeochromocytoma.

Patients who have had trans-sphenoidal hypophysectomy (removal of the pituitary gland).

Patients who have recently had nasal or sinus surgery.

Patients using other sympathomimetic decongestants concomitantly (see section 4.5).

Patients who have inflamed skin or mucous membranes of their nostrils or have scabs in their nose.

Patients suffering from cardiovascular disease (including hypertension).

Patients suffering from diabetes mellitus.

Patients suffering from hyperthyroidism.

Patients suffering from closed-angle glaucoma.

Patients currently taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping treatment (see section 4.5).

Patients taking beta-blockers (see section 4.5).

This product should not be used in patients with atrophic rhinitis or rhinitis sicca.

Children under 12 years of age.

4.4 Special warnings and precautions for use

If symptoms persist or do not improve after 7 days, a doctor should be consulted.

This medicinal product should be used for no more than 7 consecutive days to avoid rebound-effect and drug induced rhinitis (rhinitis medicamentosa).

This medicinal product should be used with caution in patients with prostatic hypertrophy (as there is a risk of acute urinary retention) and the elderly.

Consult a doctor before using this medicine in case of:

- Hepatic and renal disorders.
- Patients currently taking tricyclic antidepressants (e.g. amitriptyline, imipramine).
- Use with caution in occlusive vascular disease.
- If any of the following occur, using this medicine should be stopped:
  - Hallucinations
  - Restlessness
  - Sleep disturbances.

Keep away from eyes.

Keep all medicines out of the sight and reach of children.

This medicinal product contains benzalkonium chloride as a preservative which may cause swelling of the nasal mucosa, especially during long-term use. If such a reaction (persistent nasal congestion) is suspected, a product for nasal administration which contains no preservative should be used if possible. If such products for nasal administration are not available without preservative, the use of another dosage form should be considered. Benzalkonium chloride may also cause bronchospasm.

This medicine contains 0.4 mg benzalkonium chloride in each 1ml which is equivalent to 6 mg/15ml and 8mg/20ml. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

This medicinal product contains thiomersal (an organomercuric compound) as a preservative and therefore, it is possible that sensitisation reactions may occur.

4.5 Interaction with other medicinal products and other forms of interaction

Due to their additive effect, oxymetazoline should not be used in patients receiving treatment with other sympathomimetic products (e.g. ephedrine, pseudoephedrine), due to their additive effects.

Oxymetazoline hydrochloride should not be given to patients treated with MAOIs and/or RIMAs within 14 days of stopping treatment, including moclobemide and rasagiline as

there is a risk of hypertension if these types of drug are taken at the same time as oxymetazoline.

Oxymetazoline hydrochloride is known to interact with tricyclic antidepressants.

The effects of Bethanidine, Debrisoquine and Guanethidine may be antagonised.

Possible additive cardiovascular toxicity may occur when sympathomimeticsare given with antiparkinsonian drugs such as bromocriptine.

Since oxymetazoline hydrochloride is absorbed through the mucosa, interactions may follow topical administration. These interactions are those of the sympathomimetics in general and can include antagonism of the hypotensive effects of anti-hypertensives (including adrenergic neurone blockers and beta- blockers), increased risk of hypertension with oxytocin, appetite suppressants and amphetamine-like psychostimulants; and increased risk of ergotism with ergotamine and methysergide. There is an increased risk of dysrhythmias with cardiac glycosides. Caution is required if used with thyroid hormones.

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of use in pregnancy has not fully been established and administration of oxymetazoline hydrochloride during pregnancy should be avoided unless absolutely essential.

Animal studies do not indicate direct or indirect harmful effects with respect pregnancy, embryonal/foetal development, parturition or postnatal development. The recommended dose should not be exceeded because overdosing can decrease placental blood flow.

Caution should be exercised during pregnancy and lactation as oxymetazoline may be systemically absorbed.

Lactation

It is not known if oxymetazoline hydrochloride is excreted into breast milk. The recommended dose should not be exceeded because overdosing can reduce milk production.
A risk to the infants cannot be excluded.

Fertility

There are no known effects of oxymetazoline treatment on fertility.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

The active ingredient is usually well tolerated in normal use.

For the frequency of occurrence of side effects, the following phrases are used: 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); Very rare (<1/10,000); Unknown (cannot be estimated from the available data).

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness

System Organ Class	Undesirable effect	Frequency
Infections and infestations	Drug induced rhinitis (Rhinitis)	Unknown
Immune system disorders	Allergic reaction (Hypersensitivity)	Unknown
Metabolism and nutrition disorders	Anorexia (Decreased appetite)	Unknown
Psychiatric disorders	Nervousness (Nervousness)	Very rare
	Anxiety (Anxiety) Fear (Fear) Confusion (Confusional state) Restlessness (Restlessness) Insomnia (Insomnia) Psychotic state (Psychotic disorder) Sleep disorders in children (Sleep disorder)	Unknown
Nervous system disorders	Tremors (Tremor) Headache (Headache) Dizziness (Dizziness) Sedative effect (Sedation)	Unknown
Eye disorders	Eye irritation, dryness, discomfort or redness	Rare
	Visual disturbances (Visual impairment)	Unknown
Cardiac disorders	Arrhythmias (Arrhythmia) Tachycardia (Tachycardia) Palpitations (Palpitations)	Unknown
Vascular disorders	Vasoconstriction (Vasoconstriction) with hypertension (Hypertension) Impaired circulation to the extremities (Cold extremities) (Peripheral coldness) Reactive hyperaemia (Hyperaemia)	Unknown
Respiratory, thoracic and mediastinal disorders	Sneezing (Sneezing) Dryness in nose (Nasal dryness) Dryness in throat (Dry throat) Irrritation in nose (Nasal discomfort) Irrritation in throat (Throat irritation) Dyspnoea (Dyspnoea) Bronchospasm (as this product contains benzalkonium chloride) (Bronchospasm)	Unknown

	Rhinitis medicamentosa (Nasal congestion) Stinging or burning of the nose (Rhinalgia) Swelling of the throat (Pharyngeal oedema) Swelling of the nose (Nasal oedema)	
Gastrointestinal disorders	Dryness in mouth (Dry mouth) Irritiation in mouth (Stomatitis) Nausea (Nausea) Vomiting (Vomiting) Swelling of the lips (Lip swelling) Swelling of the tongue (Swollen tongue)	Unknown
Skin and subcutaneous tissue disorders	This medicinal product contains thiomersal (an organomercuric compound) as a preservative and therefore, it is possible that sensitisation reactions may occur (Dermatitis allergic) Local skin reactions (Skin reaction) (e.g. contact dermatitis) (Dermatitis contact) Skin discolouration (as this product contains thiomersal) (Skin discolouration) Exanthema (Rash) Skin rashes (Rash) Itching (Pruritus)	Unknown
General disorders and administration site conditions	Irritability (Irritability) Tolerance (Drug tolerance) with diminished effect (Drug effect decreased) Vasodilation in rebound congestion (Rebound effect) Weakness (Asthenia) Pain (Pain)	Unknown
Investigations	Increased blood pressure (Blood pressure increased)	Unknown

Prolonged and/or heavy use of oxymetazoline may lead to reduced effect and/or rebound congestion (rhinitis medicamentosa), cardiovascular effects and/or CNS effects.

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.

4.9 Overdose

Symptoms and signs

Symptoms of moderate or severe overdose can be mydriasis, nausea, cyanosis, fever, spasms, tachycardia, cardiac arrhythmia, cardiac arrest, hypertension, oedema of the lungs, dyspnoea, psychic disturbance. The inhibition of functions of the central nervous system such as somnolence, lowering of the body temperature, bradycardia, shock-like hypotension, apnoea and loss of consciousness is also possible.

Provided this product is used as directed, overdose is considered unlikely; however, overdosage or accidental exposure by mouth may result in CNS depression with marked reduction of body temperature and bradycardia, sweating, drowsiness and coma, particularly in children. Hypertension may be followed by rebound hypotension.

Management

A nonselective alpha-lytic such as phentolamine may be administered to depress the increased blood pressure, intubation and artificial respiration may be necessary in serious cases.

In the case of moderate or severe inadvertent oral consumption, the administration of activated carbon (absorbent) and sodium sulphate (laxative) or perhaps gastro-lavage in the case of large amounts should be undertaken.

Further treatment is supportive and symptomatic.

Vasopressor drugs are contraindicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group (ATC code): R01AA05 Decongestants and other nasal preparations for topical use. Sympathomimetics, plain.

Oxymetazoline hydrochloride is an alpha-adrenoceptor agonist which causes local vasoconstriction when applied to nasal membrane.

5.2 Pharmacokinetic properties

When applied locally to nasal mucosa, oxymetazoline acts within a few minutes and its effects last for up to 12 hours.

When administered as directed, there is no clinically relevant absorption of oxymetazoline hydrochloride.

5.3 Preclinical safety data

Preclinical data suggest that benzalkonium chloride can produce a concentration- and time-dependant toxic effect on cilia, including irreversible immobility, and can induce histopathological changes in the nasal mucosa.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride, thiomersal, sodium chloride, menthol, eucalyptol, camphor, methyl salicylate, poloxamer 188, sodium citrate (dihydrate), citric acid (anhydrous) and purified water.

6.2 Incompatibilities

None

6.3 Shelf life

36 Months

6.4 Special precautions for storage

None

6.5 Nature and contents of container

White, low density polyethylene/polypropylene copolymer 15ml bottle.

White, high density polyethylene 15ml and 20ml bottle.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Galpharm Healthcare Limited
Wrafton

Braunton
Devon
EX33 2DL
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 16028/0049

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/12/2001 / 16/05/2005

10 DATE OF REVISION OF THE TEXT

23/03/2026