SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Numark Nasal Decongestant Spray
Asda Blocked Nose Relief 0.05% w/v Nasal Spray
Morrisons Nasal Decongestant Spray
Superdrug Nasal Decongestant Spray
Wilko Decongestant 0.05% w/v Nasal Spray
Tesco Blocked Nose Relief Nasal Spray
Galpharm Blocked Nose Relief 0.05% w/v Nasal Spray
Sainsbury’s Healthcare Decongestant & hayfever 0.05% w/v Nasal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
The nasal solution contains Oxymetazoline hydrochloride 0.05% w/v
For excipients, see 6.1.

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
Panacron 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
For nasal use.
Adults and Elderly
While holding upright the spray nozzle should be inserted into each nostril in turn and squeezed firmly 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.

4.3 Contraindications
Hypersensitivity to any component of the medicinal product.

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.

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:

- High blood pressure, heart disease including angina, diabetes mellitus, hyperthyroid disease, hepatic and renal disorders.
- Patients currently taking monoamine oxidase inhibitors (MAOIs) or who have taken MAOIs in the last 14 days (see section 4.5).
- Use with caution in occlusive vascular disease.
- If any of the following occur, using this medicine should be stopped:
  - Hallucinations
  - Restlessness
  - Sleep disturbances.
- Patients who have narrow angle glaucoma.

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 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

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 sympathomimetics are 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

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 to pregnancy, embryonal/foetal development, parturition or postnatal development. It is not known if oxymetazoline hydrochloride is excreted into breast milk. The recommended dose should not be exceeded because overdosing can decrease placental blood flow and reduce milk production. Caution should be exercised during pregnancy and lactation as oxymetazoline may be systemically absorbed.

4.7 Effects on ability to drive and use machines

None

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

**Infections and infestations**
Frequency unknown:
Drug induced rhinitis (Rhinitis)

**Immune system disorders**
Frequency unknown:
Allergic reaction (Hypersensitivity)

**Metabolism and nutrition disorders**
Frequency unknown:
Anorexia (Decreased appetite)

**Psychiatric disorders**
Very rare:
Nervousness (nervousness)
Frequency unknown:
Anxiety (Anxiety)
Fear (Fear)
Confusion (Confusional state)
Restlessness (Restlessness)
Insomnia (Insomnia)
Psychotic states (Psychotic disorder)
Sleep disorders in children (Sleep disorder)

**Nervous system disorders**
Frequency unknown:
Tremors (Tremor)
Headache (Headache)
Dizziness (Dizziness)
Sedative effect (Sedation)

**Eye disorders**
Rare
Eye irritation, dryness, discomfort or redness
Frequency unknown:
Visual disturbances (Visual impairment)

**Cardiac disorders**
Frequency unknown:
Arrhythmias (Arrhythmia)
Tachycardia (Tachycardia)
Palpitations (Palpitations)

**Vascular disorders**
Frequency unknown:
Vasoconstriction (Vasoconstriction) with hypertension (Hypertension)
Impaired circulation to the extremities (cold extremities) (Peripheral coldness)
Reactive hyperaemia (Hyperaemia)

**Respiratory, thoracic and mediastinal disorders**
Frequency unknown:
Sneezing (Sneezing)
Dryness in nose (Nasal dryness)
Dryness in throat (Dry throat)
Irritation in nose (Nasal discomfort)
Irritation in throat (Throat irritation)
Dyspnoea (Dyspnœa)
Bronchospasm (as this product contains benzalkonium chloride) (Bronchospasm)
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**
Frequency unknown:
Dryness in mouth (Dry mouth)
Irritation in mouth (Stomatitis)
Nausea (Nausea)
Vomiting (Vomiting)
Swelling of the lips (Lip swelling)
Swelling of the tongue (Swollen tongue)

**Skin and subcutaneous tissue disorders**
Frequency unknown:
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 discoloration (as this product contains thiomersal) (Skin discoloration)
Exanthema (Rash)
Skin rashes (Rash)
Itching (Pruritus)

**General disorders and administration site conditions**
Frequency unknown:
Irritability (Irritability)
Tolerance (Drug tolerance) with diminished effect (Drug effect decreased)
Vasodilation in rebound congestion (Rebound effect)
Weakness (Asthenia)
Pain (Pain)

**Investigations**
Frequency unknown:
Increased blood pressure (Blood pressure increased)

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 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. 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.

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. Treatment of adverse effects is symptomatic.

5 **PHARMACOLOGICAL PROPERTIES**

5.1 **Pharmacodynamic properties**
Pharmacotherapeutic group (ATC code): S01G A04 Sympathomimetics used as decongestants.

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.

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
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
25/08/2016