Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vicks Sinex Micromist 0.05% w/v Nasal Spray, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:	% w/v
Oxymetazoline hydrochloride	0.05

Excipients:	% w/v
Benzalkonium chloride solution (50%)	0.04

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal Spray, Solution (Nasal Spray)
Non-pressurised, metered dose, aqueous nasal spray solution. Solution is a clear liquid with a slight yellowish colouration.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The symptomatic relief of acute rhinitis in allergic or upper respiratory tract infection, including the common cold or influenza.

4.2 Posology and method of administration

Topical application as a nasal spray.

Adults and children over 12 years: 1-2 sprays per nostril every 6-8 hours unless otherwise advised by your doctor.

Not to be used for children under 12 years of age.

4.3 Contraindications

Hypersensitivity to oxymetazoline or any of the other ingredients.

Where there is inflammation or lesions of the skin around the nostrils or nasal mucosa.

Not to be used for children under 12 years of age.

4.4 Special warnings and precautions for use

Patients are advised to consult their doctor before taking this medicine if they:

Have high blood pressure, heart disease including angina, diabetes, thyroid disease, hepatic or renal disorders.

Are currently taking (or have taken during the last two weeks) monoamine oxidase inhibitors (MAOIs).

Have narrow angle glaucoma.

Are a male patient with difficulty urinating due to enlarged prostate gland.

Sympathomimetic-containing products should be used with great care in patients receiving phenothiazines or tricyclic antidepressants.

Sympathomimetic-containing products should be used with caution in patients receiving digitalis, beta-adrenergic blockers, methyldopa or other anti-hypertensive agents.

The physician or pharmacist should check that sympathomimetic containing preparations are not simultaneously administered by several routes ie. orally and topically (nasal, aural and eye preparations).

This medicine contains 0.01 mg **benzalkonium chloride** in each dose (1 spray) which is equivalent to 0.2 mg/ml. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time. Long-term use may cause oedema of the nasal mucosa.

This medicine contains 0.1 mg **benzyl alcohol** in each dose (1 spray) which is equivalent to 2 mg/ml. Benzyl alcohol may cause allergic reactions. Benzyl alcohol may cause mild local irritation.

Patients are advised to use for a maximum of 7 consecutive days to avoid rebound effect and drug induced rhinitis.

If symptoms persist consult a doctor
Keep out of the reach and sight of children

4.5 Interaction with other medicinal products and other forms of interaction

Patients are advised to consult their doctor before using this product if they are taking other medicines.

Hypertensive interactions may occur between sympathomimetic amines such as oxymetazoline and monoamine oxidase inhibitors (MAOIs) (see Section 4.4).

Oxymetazoline may reduce the efficacy of beta-blocking drugs, methyl dopa or other anti-hypertensive drugs (see Section 4.4).

There is a possible increased risk of hypertension and arrhythmias when tricyclic antidepressants are given with sympathomimetics.
Possible additive cardiovascular toxicity may occur when sympathomimetics are given with antiparkinsonian drugs such as bromocriptine.

4.6 Fertility, pregnancy and lactation

Due to insufficient evidence on the use of the product in pregnancy and lactation, use of the product should be avoided unless on the advice of a physician.

4.7 Effects on ability to drive and use machines

No effects on ability to drive and use machines have been observed.

4.8 Undesirable effects

In general no severe undesirable effects are expected.
Rare (<1/1000): *Eye disorders:* Eye irritation, discomfort or redness
Respiratory: Discomfort or irritation in the nose, mouth or throat; Sneezing
Very rare (<1/10,000): *Cardiovascular*: Tachycardia, palpitations, increased blood pressure
CNS: Insomnia, nervousness, tremor, anxiety, restlessness, irritability, headache
Gastrointestinal: Nausea

Frequent or prolonged use of Vicks Sinex may lead to reduced effect and/or rebound congestion (*rhinitis medicamentosa*).

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

4.9.1 Symptoms

The symptoms of moderate or acute overdosage can include mydriasis, nausea, cyanosis, fever, tachycardia, cardiac arrhythmia, hypertension, dyspnoea, and cardiovascular failure.
CNS depression with symptoms such as decreased body temperature, bradycardia, hypotension, apnoea or loss of consciousness is possible.

4.9.2 Treatment of overdose

Symptomatic treatment of the overdosage is required. In serious cases, intubation and artificial ventilation are required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Oxymetazoline hydrochloride is an α-adrenergic imidazoline derivative, providing localised nasal vasoconstriction.

5.2 Pharmacokinetic properties

Not applicable. This product provides purely local action.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Levomenthol
Sodium citrate dihydrate
Polysorbate 80
Citric acid anhydrous
Benzyl alcohol
Benzalkonium chloride solution
Camphor (racemate)
Disodium edetate (dihydrate)
Cineole
Sorbitol 70 %
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.
After first opening: 12 months

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

15ml glass bottle (amber type III glass) mounted with an atomiser/metering unit which dispenses 0.050 g (mean spray weight) of spray at each delivery.

The atomiser comprises a polypropylene body, stainless steel spring, a high-density polyethylene piston, a polypropylene dip tube and other plastic components.
Each bottle contains a minimum of 265 sprays.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

WICK Pharma - Zweigniederlassung der Procter & Gamble GmbH
Sulzbacher Str. 40
65823 Schwalbach am Taunus
Germany

8 MARKETING AUTHORISATION NUMBER

PA2294/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 July 1998

Date of last renewal: 13 July 2008

10 DATE OF REVISION OF THE TEXT

September 2022