

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Vicks Sinex Micromist

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Name of active substance	Quantity	Unit
Oxymetazoline hydrochloride	0.05	% w/v

3 PHARMACEUTICAL FORM

Nasal spray, solution

Non-pressurised, metered dose, aqueous nasal spray solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The symptomatic relief of congestion of the upper respiratory tract due to the common cold, hayfever, and sinusitis.

4.2 Posology and method of administration

Nasal spray: for topical nasal use.

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

4.3 Contraindications

Hypersensitivity to oxymetazoline or any of the other ingredients.

Inflammation or lesions of the skin around the nostrils or nasal mucosa.

Trans-sphenoidal hypophysectomy or nasal surgery exposing the dura mater.

Concomitant use of other sympathomimetic decongestants.

Phaeochromocytoma.

Children under 12 years of age.

4.4 Special warnings and precautions for use

Consult a doctor before taking this medicine in case of:

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

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

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 away from eyes.

Keep out of the reach and sight of children.

4.5 Interaction with other medicinal products and other forms of interaction

Hypertensive interactions may occur between sympathomimetic amines such as oxymetazoline and monoamine oxidase inhibitors (MAOIs) (see Section 4.4) and/or reversible inhibition of monoamine oxidase (RIMA) and Moclobemide.

Oxymetazoline may reduce the efficacy of beta-blocking drugs, methyl dopa or other anti-hypertensive drugs including adrenergic neurone blockers.

There is a possible increased risk of hypertension and arrhythmias when tricyclic antidepressants, appetite suppressants and amphetamine-like psychostimulants are given with sympathomimetics such as oxymetazoline.

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

There is an increased risk of dysrhythmias when cardiac glycosides are given with sympathomimetics such as oxymetazoline.

There is an increased risk of ergotism when ergot alkaloids (ergotamine & methysergide) are given with sympathomimetics such as oxymetazoline.

Vicks Sinex Micromist contains benzalkonium chloride as a preservative, which may cause swelling of the mucosa, especially during long-term use.

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: Eye disorders: Eye irritation, dryness, discomfort or redness
 Respiratory: Discomfort or irritation in the nose, mouth or throat;
 Sneezing

Very rare: Cardiovascular: Tachycardia, palpitations, increased blood pressure
 CNS: Insomnia, nervousness, tremor, anxiety, restlessness, irritability,
 headache
 Gastrointestinal: Nausea

Prolonged and/or heavy use of Vicks Sinex Micromist may lead to reduced effect and/or rebound congestion (rhinitis medicamentosa), cardiovascular effects and 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

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.

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.

Pharmacotherapeutic group: Sympathomimetics, plain

ATC code: R01AA05

Mechanism of action

Oxymetazoline is a direct-acting sympathomimetic amine. It acts on alpha-adrenergic receptors in the vessels of the nasal mucosa producing vasoconstriction and decongestion. The onset of action normally occurs within 2-30 minutes of administration and the duration of action is 6-8 hours.

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

Menthol (levo)

Sorbitol

Sodium citrate dihydrate

Benzyl alcohol

Citric acid anhydrous

Polysorbate 80

Benzalkonium chloride solution (50%)

Camphor (racemate)

Disodium edetate (dihydrate)

Eucalyptol

Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

4 years

After opening: 12 months

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

15ml glass bottle (amber type III glass) mounted with an atomiser/metering unit which delivers 25µg Oxymetazoline Hydrochloride per spray. Each bottle contains a minimum of 265 sprays.

The atomiser comprises a polypropylene body, stainless steel spring, a high-density polyethylene piston, a polypropylene dip tube and other plastic components.

6.6 Special precautions for disposal

Two actuations of the pump are required before first usage of this medicine. Following periods of storage of greater than one week one actuation is required to prime the pack before use.

7 MARKETING AUTHORISATION HOLDER

Procter & Gamble (Health & Beauty Care) Limited
The Heights
Brooklands
Weybridge
Surrey
KT13 0XP
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00129/0133

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

08/12/2000

10 DATE OF REVISION OF THE TEXT

26/08/2022