1. NAME OF THE MEDICINAL PRODUCT

Vicks Sinex, 0.5 mg/ml, nasal spray solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Oxymetazoline hydrochloride 0.5 mg/ml
1 spray (50µl) contains approximately 25 micrograms oxymetazoline hydrochloride.

Excipients with known effect: Benzalkonium chloride 0.2 mg/ml (0.01 mg/spray), and benzyl alcohol 2 mg/ml (0.1mg/spray).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Nasal spray, solution
A clear liquid preparation

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of nasal congestion for adults, adolescents and children over 6 years.

4.2 Posology and method of administration

Posology
Adults and children over 10 years: 1-2 sprays up each nostril maximum 2-3 times daily.

Paediatric population
Children aged 6-10 years: 1 spray up each nostril maximum 2-3 times daily.

Not intended for children below the age of 6.

Vicks Sinex should not be used for more than 7 days in a row.

Method of administration: nasal use.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- In patients taking monoamine oxidase inhibitors (MAOIs) or who have taken MAOIs in the previous two weeks.
- In patients with narrow-angle glaucoma.
- In patients following a trans-sphenoidal hypophysectomy.
- Where there is inflammation of the skin and mucosa of the nasal vestibule and encrustation (rhinitis sicca).
- In patients with acute coronary disease or cardiac asthma.

4.4 Special warnings and precautions for use

- As oxymetazoline is a vasoconstrictor, caution should be exercised in patients with hypertension, ischemic heart diseases including angina, hyperthyroidism, diabetes mellitus, increased intraocular pressure and prostatic hypertrophy.
- In patients with phaeochromocytoma.
- Vicks Sinex should be used for a maximum of 7 consecutive days. The recommended dose should not be exceeded. Usage for longer than recommended may lead to reduced effect of a dose (tachyphylaxis) or rebound-effect due to reactive hyperaemia.
- If symptoms worsen or do not improve, a physician or qualified health care practitioner should evaluate the clinical situation.
- This medicine contains benzalkonium chloride. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time. 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.
- This medicine contains benzyl alcohol. Benzyl alcohol may cause allergic reactions and/or mild local irritation.
- Direct contact with the eyes should be avoided.

4.5 Interaction with other medicinal products and other forms of interaction

This product should not be used in combination with MAOIs, or for up to 2 weeks after taking MAOIs as there is a risk of interactions leading to hypertension. See section 4.3.

This product is known to interact with tricyclic antidepressants with a possible increased risk of hypertension and arrhythmias.

The effects of beta-blockers or other antihypertensive drugs e.g. methyl dopa, bethanidine, debrisoquine and guanethidine may be antagonised.

4.6 Fertility, pregnancy and lactation

Pregnancy
For oxymetazoline hydrochloride no clinical data on exposed pregnancies are available.
Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.

Breast-feeding
For oxymetazoline hydrochloride there are no clinical data available indicating if it is excreted into breast milk.
The recommended dose should not be exceeded because overdosing can decrease placental blood flow and reduce milk production.

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

Vicks Sinex has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Within the system organ classes, adverse reactions are listed under headings of frequency (number of patients expected to experience the reaction), using the following categories: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000) and not known (cannot be estimated from the available data).
Data from clinical trials with Vicks Sinex are limited. Therefore, additional adverse reactions reported spontaneously from post marketing data are also included in the table below. The frequency for these are not known (cannot be estimated from the available data)

System Organ Class	**Adverse Drug Reaction**
Nervous system disorders	
Rare (<1/1000)	anxiety, sedative effect, irritability, sleep disorders.
Cardiac disorders	
Rare (<1/1000):	tachycardia, palpitations, increased blood pressure
Respiratory, thoracic and mediastinal disorders	
Uncommon (1/100 - 1/1000):	Sneezing, dryness and irritation in nose, mouth and throat, reactive hyperaemia.
Gastrointestinal disorders	
Not known	Nausea
General disorders and administration site conditions	
Rare (<1/1000):	Tachyphylaxis. headache, exanthema and visual disturbances

Use for longer than recommended may lead to reduced effect and/or rebound congestion.

Reporting of suspected adverse reactions
Reporting of 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 national reporting system listed in Appendix V*.

4.9 Overdose

The clinical picture may be unclear, with episodes of hyperactivity alternated with episodes of depression of the central nervous system and of the cardiovascular and pulmonary system.

Symptoms of 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, shocklike hypotension, apnoea, and loss of consciousness is also possible.

Treatment of overdosage:
Symptomatic treatment of overdose is required. A nonselective alpha-lytic such as phentolamine may be administered as antidote to depress the increased blood pressure. If required, initiate fever lowering measures, anticonvulsive therapy and oxygen ventilation. 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 immediately as oxymetazoline may be absorbed.
Further treatment is supportive and symptomatic.
Vasopressor drugs are contraindicated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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.
Onset of action is within minutes and lasts up to 12 hours.

5.2 Pharmacokinetic properties

Absorption
With local use on the nasal mucosa, there is no clinically relevant absorption of oxymetazoline hydrochloride.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of repeated dose toxicity or toxicity to reproduction. Vicks Sinex Nasal Spray has not been tested for genotoxicity or carcinogenicity. 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

Sorbitol
Sodium citrate (for pH-adjustment)
Polysorbate 80
Benzyl alcohol
Citric acid, anhydrous (for pH-adjustment)
Benzalkonium chloride solution
Acesulfame potassium
Levomenthol
Cineole
Disodium edetate
Aloes dry extract
Levocarvone
Water, purified.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Glass bottle 15 ml: 3 years

After first opening of the bottle: 12 months

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

Brown Type III glass bottle 15 ml with a metering pump (polypropylene).
Each bottle contains a minimum of 265 sprays.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

<To be completed nationally>

8. MARKETING AUTHORISATION NUMBER(S)

<To be completed nationally>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 August 1997
Date of last renewal: 16 June 2015

<To be completed nationally>

10. DATE OF REVISION OF THE TEXT

<To be completed nationally>
9 June 2023