SUMMARY OF PRODUCT CHARACTERISTIC (SMPC)

1. NAME OF THE MEDICINAL PRODUCT

Nasivin 0.025% Nasal Drops.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Item no.	Material Name	Scale (mg/mL)
	Active Ingredients:	
1.	Oxymetazoline HCL	0.250

3. PHARMACEUTICAL FORM

Nasal Drops, Solution

Description: Clear, colourless to faint yellow.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Children 2 – 5 years old: 2 - 3 drops of **Nasivin** 0.025% into each nostril every 10 – 12 hours, maximum 2 doses in 24 hours, or as directed by the physician.

4.3 Contraindications

Nasivin should not be used:

- By patients taking monoamine oxidase inhibitors (MAOIs) or in patients who have taken MAOIs in the previous two weeks.
- In patients with narrow-angle glaucoma. **Nasivin** should not be used by patients after trans-sphenoidal hypophysectomy.
- In case of hypersensitivity to the active substance or to any of the excipients.
- Where there is inflammation of the skin and mucosa of the nasal vestibule and encrustation (rhinitis sicca).
- By patients with acute coronary disease or cardiac asthma.

4.4 Special warnings and precautions for use

- Caution should be exercised in case of hypertension, cardiac diseases including angina, hyperthyroidism, diabetes mellitus and prostatic hypertrophy.
- Do not exceed the recommended dose.
- If symptoms worsen or do not improve after 3 days, physician should re-evaluate clinical situation.

- **Nasivin** should be used for a maximum of 7 consecutive days to avoid rebound-effect and drug induced rhinitis.
- The preservative (benzalkonium chloride) contained in **Nasivin** can 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.

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

4.6 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 the drops may lead to reduced effect and/or rebound congestion (rhinitis medicamentosa), cardiovascular effects and/or CNS effects.

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. The product provides purely local action.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Inactive Ingredients:
1. Edetate Disodium (Edetic Acid Disodium Salt. $2H_2O$)
2. Benzalkonium Chloride solution 50%
3. Sodium Hydroxide Solution 0.1M
4. Monobasic Sodium Phosphate (Sodium Dihydrogen Phosphate. $2H_2O$)
5. Dibasic Sodium Phosphate (Disodium Hydrogen Phosphate. $12H_2O$)
6. Purified Water

6.2 Incompatibilities

None

6.3 Shelf life

60 months from the date of manufacturing

6.4 Special precautions for storage

Store at room temperature not exceeding 25°C

6.5 Nature and contents of container

10mL solution in an amber colored glass bottle with dropper assembly, packed in a printed carton along with a leaflet.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Gulf Pharmaceutical Industries - Julphar
Digdaga, Airport Street
Ras Al Khaimah - United Arab Emirates
P.O. Box 997
Tel. No.: (9717) 2 461 461
Fax No.: (9717) 2 462 462

8. MARKETING AUTHORISATION NUMBER(S)

09132/08202/REN/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Dec 4, 2023

10. DATE OF REVISION OF THE TEXT

06. April. 2015