SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nezebi 0.5 mg/ml nasal spray, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of the solution contains 0.5 mg of oxymetazoline hydrochloride.

For a full list of excipients, see section 6.1.

Each spray has volume of 50 microliter which contains 0,025 mg oxymetazoline hydrochloride.

3 PHARMACEUTICAL FORM

Nasal spray, solution
Clear, colourless to slightly coloured solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Rhinitis and as a decongestant for sinusitis.

4.2 Posology and method of administration

Posology

Age from	*Strength*	*Dosage*
10 years and older	0.5 mg/ml	2 sprays in each nostril 2–3 times a day.

Nezebi nasal spray can be used for a maximum of 10 consecutive days.
The recommended daily dosage or the specified number of doses should not be exceeded (see section 4.4).

Paediatric population
Nezebi nasal spray is not appropriate for children under the age of 10 years.

Method of administration
Nasal use.
Before using: when the nasal spray is used for the first time the pump must be primed. Keep the bottle upright and spray 5 times in the air until the spray is homogenous. If the pump has not been used for a long time, it should be recharged with 3 sprays in air.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
The product should not be used in patients with atrophic rhinitis or rhinitis sicca.

4.4 Special warnings and precautions for use

The recommended dose should not be exceeded. The prolonged or excessive use of the product may cause rhinitis medicamentosa.
If the symptoms aggravate or persist during the use of this medicinal product, a doctor or a qualified health care practitioner should be consulted.

The product should be used with caution in:
• cardiovascular disease (e.g. ischaemic cardiac disease)
• hypertension
• diabetes mellitus
• pheochromocytoma
• prostatic hypertrophy
• angle-closure glaucoma
• hyperthyroidism
• patients taking tricyclic and tetracyclic antidepressants (e.g. amitriptyline, imipramine), or monoamine-oxidase inhibitors (MAOI) (see also Section 4.5).

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of tricyclic or tetracyclic antidepressants (e.g. amitriptyline, imipramine) or monoamine-oxidase inhibitors (MAOI) or within 14 days of ceasing such treatment may cause a hypertensive crisis.
Oxymetazoline may change the effect of some beta-blockers.

Oxymetazoline should not be used in patients receiving treatment with other sympathomimetic products (e.g. ephedrine, pseudoephedrine), due to their additive effects.

4.6 Fertility, pregnancy and lactation

Pregnancy
There is limited data available on the use of oxymetazoline in pregnant women. The product should not be used during pregnancy unless the potential benefit of treatment to the mother outweighs the possible risks to the developing foetus.

Breastfeeding
No information regarding possible excretion of oxymetazoline hydrochloride into breast milk is available. No studies have been conducted.

Fertility
There are no known effects of oxymetazoline treatment on fertility.

4.7 Effects on ability to drive and use machines

Oxymetazoline has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The following adverse reactions are tabulated by MedDRA System Organ Class and frequency. The following convention has been utilised for the classification of undesirable effects: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1000), very rare (<1/10,000), not known (cannot be estimated from available data).

Uncommon (≥1/1 000, <1/100)	*Respiratory, thoracic and mediastinal disorders:* Sneezing, dry mouth and throat.
Rare (≥1/10 000, <1/1,000)	*Psychiatric disorders:* Restlessness, irritability, sleep disturbances in children. *Respiratory, thoracic and mediastinal disorders:* Local irritation.

Rhinitis caused by the medicinal product (rhinitis medicamentosa) may occur during long term use.

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 national reporting system listed in Appendix V*.

4.9 Overdose

Toxicity: 1–3.75 mg taken orally by 2-year-old children caused no or mild symptoms.
Symptoms: Headache, CNS suppression, coma, possibly convulsions, hypothermia, hypertension, peripheral vasoconstriction, cold extremities, bradycardia, mydriasis, bronchospasm.
Treatment: When applicable, gastric lavage at an early stage. Activated charcoal. Monitoring of breathing and circulation. Oxygen, and if necessary, respirator therapy. Diazepam for possible convulsions. In other cases, symptomatic treatment should be given.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Decongestants for topical use, adrenergics
ATC code: R01AA05

Nezebi contains oxymetazoline hydrochloride, which is an alfa receptor agonist with decongestant effects. The decongestant effects are due to the constriction of smooth muscles in nasal mucosal veins. The effects of oxymetazoline hydrochloride are achieved already within a few minutes of application and lasts for up to 12 hours.

The solution contains also dexpanthenol that has hygroscopic properties and hydrates the nasal mucosa.

5.2 Pharmacokinetic properties

Absorption
Topical imidazoline derivatives have minimum systemic absorption if used according to the recommended dosages and route of administration.

5.3 Preclinical safety data

-

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dexpanthenol
Disodium edetate (E386)
Sodium dihydrogen phosphate dihydrate (E339)
Disodium phosphate dihydrate (E339)
Sodium chloride
Purified water

6.2 Incompatibilities

-

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

7,5 ml plastic bottle (HDPE), PP nasal applicator with a metered-dose spray pump (the material in contact with the solution: HDPE, PP, PE, stainless steel) with a PP protective cap.

6.6 Special precautions for disposal and other handling

-

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:

[To be completed nationally]

10 DATE OF REVISION OF THE TEXT

27 Dec 2022