# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

NASOL® NEBULISER

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of NASOL® NEBULISER contains
Naphazoline Hydrochloride 1.0 mg
Chlorpheniramine Maleate 2.5 mg
in an aqueous isotonic solution.

For excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Nasal spray, solution
The spray is a clear, colorless to light yellow solution.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Relief of nasal congestion due to the common cold, hay fever, rhinitis and sinusitis.

### 4.2 Posology and method of administration

NASOL® NEBULISER should not be used in children aged less than 6 years old.

Children 6-12 years 1 spray into each nostril every 4 – 6 hours as needed.

Adults, children over 12 years 1-2 sprays into each nostril every 4 – 6 hours as needed.

Route of administration: Nasal use.

The recommended dose should not be exceeded, especially in children and the elderly.

### 4.3 Contraindications

Do not use in patients with narrow-angle glaucoma, hypersensitivity to imidazoline-derivative sympathomimetic amine or any ingredients in this product.

**4.4 Special warnings and precautions for use**

− Frequent or prolonged use of this medicine may cause recurrence or exacerbation of nasal congestion. Therefore, should not be used for longer than 3 days.

− Use with caution in patients with diabetes, asthma, cardiovascular disease, hypertension, hyperthyroidism, hypertrophy of prostate gland, epilepsy, glaucoma, raised intra-ocular pressure, urinary retention, pyloduodenal obstruction, hepatic disease, bronchitis

− Use with caution in children and elderly

− Should not be used concomitantly with MAOIs

**4.5 Interaction with other medicinal products and other forms of interaction**

This medicine may increase the adverse effects when used with central nervous system depressant medicine such as MAO Inhibitor, tricyclic antidepressant and alcohol.

**4.6 Fertility, pregnancy and lactation**

***Fertility***

It is not known whether this medicine can affect reproduction capacity in humans.

***Pregnancy***

Animal studies have not been conducted and it is not known whether the drugs can cause fetal harm when administered to a pregnant woman. There are no adequate data from the use of this medicine in pregnant women. Using the third trimester may result in reactions in the newborn or premature neonates. Therefore, this medicine should be used during pregnancy only when clearly needed. Not to be used during pregnancy unless considered essential by a physician.

***Lactation***

It is not known whether this medicine is distributed into milk. This medicine may inhibit lactation and may be secreted in breast milk. Caution should be exercised when this medicine is administered to a breast-feeding woman. Not to be used during lactation unless considered essential by a physician.

**4.7 Effects on ability to drive and use machines**

NASOL® NEBULISER may cause drowsiness, temporary blurred vision, if affected, do not drive or operate machinery.

**4.8 Undesirable effects**

− Nasal mucosa irritation, dryness, burning, stinging, sneezing or increased nasal discharge may occur.

− Very rare: metabolism and nutrition disorder: hyperglycemia
nervous system disorders: drowsiness, headaches and dizziness, anxiety
cardiac disorders: cardiac arrhythmia
vascular disorders: increased blood pressure
GI disorders: nausea
General disorders: weakness, excessive sweating

**4.9 Overdose**

Symptoms and Signs

- Naphazoline

Naphazoline has a narrow therapeutic to toxic window and intoxication may occur at a dose of 0.05 mg/kg body weight. Inappropriate use can cause vitally threatening cardiovascular symptoms (arterial hypertension with reflex bradycardia define as a heart rate under 60 bpm and possible ischaemia of vital functions), pulmonary and central nervous symptoms (drowsiness to coma, persisting cardiovascular hypotension, reduced respiration rate, pulmonary edema, hypothermia, mydriasis, hyperhydrosis and transient excitation hyperreflexia. However, absorption and distribution in children depending on their age. Case of overdose are rare after the age of six since by that age, the mechanisms of adrenergic agonists inactivation are completely formed.

- Chlorpheniramine

The estimated lethal dose of chlorpheniramine is 25 to 50 mg/kg body weight. Symptoms and signs include sedation, paradoxical excitation of the CNS, toxic psychosis, convulsions, apnea, anticholinergic effects such as dry mouth, dystonic reactions and cardiovascular collapse including arrhythmias

According to the total volume of this medicine, total amount of naphazoline is 15 mg and chlorpheniramine is 37.5 mg per bottle, these symptoms above are unlikely to happen when recommended dose are administered.

Treatment

- Naphazoline

Since no specific antidote is available. In case of overdosage or intoxication, symptomatic drug therapy with intravenous administration of 5 mg phentolamine for adults and 1 mg phentolamine for infants has to be done. Phentolamine, an alpha-adrenoceptor antagonist, acting against peripheral and central side effects.

- Chlorpheniramine

Symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions and fluid and electrolyte balance. If overdosage is by the oral route, treatment with activated charcoal should be considered provided there are no contraindications for use and the overdose has been taken recently (treatment is most effective if given within an hour of ingestion). Treat hypotension and arrhythmias vigorously. CNS convulsions may be treated with i.v. diazepam. Haemoperfusion may be used in severe cases.

# 5. PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sympathomimetics, combinations excl. corticosteroids
ATC code: R01AB02

Naphazoline hydrochloride stimulates alpha-adrenergic receptors in the arterioles of the nasal mucosa to produce vasoconstriction to relieve nasal congestion.

Chlorpheniramine maleate is an antihistamine used to relieve symptoms of allergy and the common cold.

## 5.2 Pharmacokinetic properties

Chlorpheniramine maleate is metabolized in the liver, parent drug and metabolites are excreted in urine. Nasally applied chlorpheniramine maleate was readily absorbed, reaching peak plasma levels after 0.25 to 3.0 hours. The dose-normalized estimated mean Cmax values were 1.12 mg and 2.24 mg nasal dose. The dose-normalized estimated mean AUC(0-infinity) values were 1.12 and 2.24 mg nasal dose. The estimated treatment ratios (nasal dose to tablet) of the dose-normalized values for the 1.12 mg nasal dose were 1.15 (90% CI: 1.0-1.32) and 1.02 ( 90% CI: 0.88-1.18) for Cmax and AUC(0-infinity), respectively, for the 2.24 mg nasal dose they were 0.98 (90% CI: 0.85-1.13) and 0.99 (90% CI: 0.85-1.13) for Cmax and AUC(0-infinity), respectively.

Naphazoline hydrochloride is not well defined. Well planned studies on the pharmacokinetics, such as distribution and elimination, and dosing of these compounds are lacking. Local vasoconstriction usually occurs within 10 minutes and may persist for 2-6 hours. Occasionally, enough naphazoline may be absorbed to produce systemic effects.

### 5.3 Preclinical safety data

No data available

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Anhydrous citric acid
Edetate disodium
Monobasic sodium phosphate (dihydrate)
Dibasic sodium phosphate (heptahydrate)
Glycerin
Benzalkonium chloride (50% aqueous solution)
Purified water

### 6.2 Incompatibilities

None.

### 6.3 Shelf life

24 months

### 6.4 Special precautions for storage

Store below 30°C

### 6.5 Nature and contents of container

Available in plastic bottle 15 ml

### 6.6 Special precautions for disposal

Keep all medicines out of the reach of children

## 7. MARKET AUTHORISATION HOLDER

OLIC (Thailand) Limited
166 Bangpa-In Industrial Estate, Udomsorayuth Road, Moo 16, Bangkrason, Bangpa-In, Ayutthaya, 13160, Thailand
Sole agent : Thai Drugs & Chemicals Ltd. Part.
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## 8. MARKETING AUTHORISATION NUMBER(S)

2A XX/XX

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

DD/MM/YYYY

## 10. DATE OF REVISION OF THE TEXT

2 October 2023