

**1. Name of the medicinal product:**

**Nostamine** Eye & Nasal Sterile Solution

**2. Qualitative and quantitative composition:**

Each 1 ml contains:

Naphazoline HCl ..... 0.5 mg

Chlorpheniramine maleate..... 0.5 mg

For excipients see section 6.1

**3. Pharmaceutical form:**

A clear colorless solution preserved in a tight, light resistance plastic dropper bottles.

**4. Clinical particulars:**

**4.1 Therapeutic indications:**

**Nose:** Common cold, symptomatic treatment of rhinitis, sinusitis and allergic rhinitis.

**Eye:** Spring catarrh and allergic manifestation of the eye.

**4.2 Posology and Method of Administration**

**Nose:** 2 drops 4 times daily in each nostril.

**Eye:** 1-2 drops 3 - 6 hours.

**4.3 Contraindications:**

Narrow angle glaucoma.

**4.4 Special warnings and precautions for use:**

None

**4.5 Interaction with other medicinal products:**

None

**4.6 pregnancy and lactation:**

None.

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

None.

**4.8 Undesirable effects:**

Uncommon; mild transient stinging with frequent application may occur.

**4.9 Overdose:**

No action other than medical observation should be necessary.

**5. Pharmacological properties:**

**5.1 Pharmacodynamic properties:**

**Nostamine** contains naphazoline HCL which has a potent quick vasoconstrictor effect and chlorpheniramine maleate which has a marked antihistaminic effect.

**Nostamine** produces a rapid and prolonged decongestion of the nasal mucosa and conjunctiva.

**5.2 Pharmacokinetic properties:**

None.

**5.3 Preclinical safety data**

There are no pre-clinical data.

**6. Pharmaceutical particulars:**

**6.1 List of excipients:**

Sodium citrate dihydrate, boric acid, benzalkonium chloride, disodium edetate, purified water.

**6.2 Incompatibilities:**

None known

**6.3 Shelf life:**

3 years.

**6.4 Special precautions for storage:**

Store at temp. 15° - 30° C.

It should be used within 1 month after opening.

**6.5 Nature and contents of container:**

Bottles of 10 ml and 15 ml.

**6.6 Special precautions for disposal and other handling:**

Do not use if the drops change color or become cloudy.

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

**7. Marketing authorisation holder:**

EIPICO

**8. Date of revision of the text**

August 2024