SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Brand Name	:	**NASALOX 0.05% NASAL DROPS 10 ML**
Generic Name	:	Oxymetazoline Hydrochloride
Pharmaceutical Dosage Form	:	Nasal Drops (sterile)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 mL sterile solution contains Oxymetazoline Hydrochloride 5.00 mg.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Nasal Drops (sterile)

Clear transparent solution in 10 mL round ivory color plastic dropper bottle with plug and cap.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Nasalox 0.05% nasal drops is indicated for the treatment of

• Relief of nasal congestion associated with

•Acute and chronic rhinitis

• Common cold

• Sinusitis

4.2 Posology and method of administration

Adults: 2 to 3 drops of 0.05% Oxymetazoline in each nostril twice daily, in the morning and evening for 3-5 days.

Children over 6 years of age: 2 to 3 drops of 0.025% Oxymetazoline in each nostril twice daily, in the morning and evening for 3-5 days. Dosage for children younger than 6 years of age has not been established. Oxymetazoline should generally be used for no longer than 3-5 days.

Missed Dose: If a dose missed then take it as soon as possible. However, if it is almost time for next dose, skip the missed dose and go back to regular dosing schedule. Do not take double doses.

4.3 Contraindications

Contraindicated in patients with hypersensivity to Oxymetazoline Hydrochloride.

4.4 Special warnings and special precautions for use

Patients sensitive to other nasal decongestants may be sensitive to this medication also.

4.5 Interaction with other FPPs and other forms of interaction

Oxymetazoline causes hypertensive crisis if used simultaneously with MAO inhibitor or Tricyclic antidepressant.

4.6 Fertility, pregnancy and lactation

Pregnancy: Pregnancy Category C. Avoid during pregnancy.

Lactation: It is not known if this agent is excreted in breast milk, so caution should be exercised when administering to a nursing mother.

4.7 Effects on ability to drive and use machines

It is suggested to consult with the doctor or pharmacist.

4.8 Undesirable effects

When this medicine is used for short period of time at low doses, side effects are usually rare. However, stinging, burning, sneezing, increased nasal discharge, drying of the nostrils, and altered taste may occur.

4.9 Overdose

Following a proper application, systemic action is unlikely. If, however, some of the drops are swallowed, systemic effect can be produced. Symptoms include rapid, irregular heartbeat, headache, dizziness, increased sweating, and nervousness. Such symptoms are more likely to be seen in young children.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sympathomimetics, plain.

ATC-code: R01AA05

Mechanism of action

Oxymetazoline is a sympathomimetic agent which has local vasoconstrictive effects on the nasal mucosa, decreasing nasal congestion. Nasalox nasal spray is called a "non-dripping "pharmaceutical form, since its viscosity thickens after spraying and thus stays on the nasal mucosa for longer periods of time than standard water solution. Clinical studies have shown that the effects of oxymetazoline appear within a couple of minutes and may last up to 12 hours after administration.

Oxymetazoline Hydrochloride is an imidazoline derivative sympathomimetic amine. It is a direct agonist at α-adrenoreceptors but has no actions on β-adrenoreceptors. It is used as a topical agent on the nasal mucosa, produces a rapid and long-acting vasoconstriction of the arterioles, thus reducing blood flow and diminishing swelling of the mucosa. This results in improved potency of the airway and better drainage of nasal sinuses.

5.2 Pharmacokinetic properties

Oxymetazoline enters tissues rapidly and local vasoconstriction is normally achieved within 5-10 minutes of intranasal administration. The full effect lasts for 5-6 hours and then gradually subsides over the next 6 hours. Plasma half-life is 5-8 days with 30% of any absorbed drug being excreted in the urine unchanged and 10% being excreted in the faces.

5.3 Preclinical safety data

Oxymetazoline solutions inhibit middle ear pathogens and are not ototoxic.

Objectives:

This study was performed to explore the antimicrobial activity of two commercially available Oxymetazoline hydrochloride preparations against the common pathogens of otitis media to and demonstrate the lack of ototoxicity of these agents and of United States Pharmacopeia (USP) oxymetazoline in a standard animal model.

Methods:

Disc diffusion assays and minimum inhibitory concentration studies against American Type Culture Collection reference strains of common middle ear pathogens were used to evaluate the antimicrobial activity of oxymetazoline solutions and fluoroquinolone drops, and outer hair cell counts were performed on scanning electron micrographs of guinea pig basal cochlear segments after chronic exposure to oxymetazoline solutions and positive and negative controls.

Results:

Oxymetazoline nasal spray and eyedrops had activity against all species tested except Haemophilus influenzae and Pseudomonas aeruginosa. The USP oxymetazoline had limited antimicrobial activity. Oxymetazoline nasal spray, oxymetazoline eyedrops, and USP oxymetazoline had ototoxicity profiles indistinguishable from that of the saline solution control.

Conclusions:

Commercially available oxymetazoline solutions are active against several of the common pathogens of otitis media. This antimicrobial activity is not due to oxymetazoline, and is more likely due to preservatives present in the solutions. The solutions tested are not ototoxic to guinea pig outer hair cells. Oxymetazoline solutions are potential substitutes for broad-spectrum antibiotic drops after tympanostomy tube placement.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Bezalkonium Chloride Solution, 50%

Disodium Edetate

Borax (Sodium Borate)

Boric Acid

Sodium Chloride (For Sterile)

Water for Injections

6.2 Incompatibilities

In the formulation we have used the common excipients: Bezalkonium Chloride Solution, 50%, Disodium Edetate, Borax (Sodium Borate), Boric Acid, Sodium Chloride (For Sterile) & Water for Injection (WFI) are widely used in pharmaceutical industry for a long time. Moreover, the stability study at accelerated and long-term condition was found satisfactory. In addition, Physico-chemical parameters comply with the specification during product release and stability study. So, it could be concluded that excipients used in the drug product are compatible with drug substances.

6.3 Shelf life

2 years (24 Months from the date of manufacturing)

6.4 Special precautions for storage

Store below 30°C, protect from direct sunlight & heat. Don not freezes. Keep out of the reach of children.

6.5 Nature and contents of container

10 ml Ivory color plastic dropper bottle with plastic cap and plug.

The packaging material i.e container & plug material is Low Density Polyethylene(LDPE) and cap material is the combination of Low Density Polyethylene (LDPE) & High Density Polyethylene (HDPE).

6.6 Special precautions for disposal and other handling

During use of the dropper, do not touch the dropper tip to surfaces since this may contaminate the solution. After one month of opening do not use the medicine of dropper. Dispose the empty container in waste bin.

7. MARKETING AUTHORISATION HOLDER

7.1 Name and address of manufacturer

Name	:	**GENERAL Pharmaceuticals Ltd. (Unit: 2)**
Address	:	Karolshurichala, Kaliakair, Gazipur, Bangladesh
E-mail	:	gplfactoryu2@generalpharma.com

8. MARKETING AUTHORISATION NUMBER(S)

04280/5585/NMR/2017

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30-01-2019

10. DATE OF REVISION OF THE TEXT

03-07-2022