SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product

MICROSOL

2. Quality and Quantitative Composition

Naphazoline Hydrochloride USP.... 0.056% w/v

Chlorphenamine Maleate BP ..... 0.01 % w/v

Boric Acid BP ..... 1.25% w/v

Sodium Chloride BP 0.05% w/v

Zinc Sulphate USP 0.12% w/v

Chlorbutol 0.5% w/v (As Preservative)

Water for injections BP ..... q.s

3. Pharmaceutical Form

Ophthalmic Solution

4. Clinical PARTICULARS

4.1 Therapeutic indications:

It is used for temporarily relieves itching and redness caused by pollen, ragweed, grass, animal hair and dander.

4.2 Posology and method of administration:

Adults and children 6 years of age and older: instill 1 or 2 drops in affected eye(s) up to 4 times daily.

Children under 6 years: ask a doctor.

4.3 Contraindications:

Naphazoline is contraindicated in patients with known hypersensitivity to the drug. Patients with glaucoma should be advised not to use Naphazoline hydrochloride ophthalmic solutions except under the advice and supervision of a physician. Ophthalmic solutions of the drug should not be used in patients with angle-closure glaucoma. Fixed combinations containing Naphazoline hydrochloride and antazoline are contraindicated while soft contact lenses are being worn.

Patients using zinc sulfate ophthalmic solutions should be advised to discontinue the drug and consult a physician if ocular pain or visual changes occur, they experience continued ocular redness or irritation, or the condition worsens or persists for more than 3 days.

4.4 Special warning and precautions:

Warnings: if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a physician. Do not use in children under 6 years of age unless directed by a physician. If this solution changes color or becomes cloudy, do not use. Overuse of this product may produce increased redness of the eye.

If you are sensitive to any ingredient in this product, do not use. To avoid contamination, do not touch tip of container to any surface. Replace cap after using.

Patients using zinc sulfate ophthalmic solutions should be advised to discontinue the drug and consult a physician if ocular pain or visual changes occur, they experience continued ocular redness or irritation, or the condition worsens or persists for more than 3 days.

4.5 Interactions with Other Medicaments

Concurrent use of maprotiline or tricyclic antidepressants with "Naphazoline" hydrochloride may potentiate the pressor effects of "Naphazoline".

Patients being treated with monoamine oxidase (MAO) inhibitors may experience a severe hypertensive reaction if administered with a sympathomimetic drug. Although this reaction has not specifically been reported with "Naphazoline", the possibility of such an interaction should be considered.

4.6 Fertility, pregnancy and lactation

Pregnancy

Animal studies have not been conducted with Naphazoline hydrochloride, and it is not known whether the drug can cause fetal harm when administered to a pregnant woman. Therefore, Naphazoline hydrochloride should be used during pregnancy only when clearly needed.

Fertility

It is not known whether Naphazoline hydrochloride can affect reproduction capacity in humans.

Lactation

It is not known whether Naphazoline hydrochloride is distributed into milk. Because many drugs are distributed into milk, caution should be exercised when this drug is administered to a breast-feeding woman.

4.7 Effects on ability to drive and use machine:

Do not drive or operate machinery if vision is blurred.

4.8 Undesirable effects:

Blurring of vision, mild stinging and/or irritation, mydriasis and increased or decreased intraocular pressure. When used in high doses in elderly, Naphazoline may liberate pigment granules from the iris.

4.9 Overdose:

Over dosage or accidental administration by mouth may cause depression of CNS, reduction of body temperature, bradycardia, sweating, drowsiness and coma, particularly in children. Hypertension may be followed by rebound hypotension. In addition, over dosage may cause increased redness of the eye. Treatment of side-effects is symptomatic.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties:

Naphazoline, an imidazoline derivative is a sympathomimetic with α-adrenergic activity. It produces vasoconstriction. When applied topically to mucous membranes, it reduces swelling and congestion. It is often used in combination with pheniramine, an allylamine derivative antihistamine, in ophthalmic preparations.

Zinc sulfate exhibits astringent and weak antiseptic activity. These effects may result from precipitation of protein by the zinc ion. Zinc sulfate produces mild vasodilation in concentrations used in ophthalmic preparations; the drug has no decongestant action. Zinc sulfate exhibits mild astringent activity by precipitating protein and clearing mucus from the outer surface of the eye.

5.2 Pharmacokinetic Properties:

Onset: Local vasoconstriction: Within 10 minutes

Duration: Local vasoconstriction: 2-6 hr

5.3 Preclinical safety Data:

None stated

6. Pharmaceutical Particulars

6.1 List of excipients:

Boric acid

Sodium chloride

Chlorbutol

Disodium Edetate

Trisodium citrate

Sodium hydroxide

Water for injection

6.2 Incompatibilities:

Not applicable

6.3 Shelf life:

2 years

6.4 Special precautions for storage:

Store below 30°C. Protect from light

6.5 Nature and contents of container:

10 ml BFS container Sterile HIPS Grey caps with in a carton

6.6 Special precautions for disposal

No special requirements

SUMMARY OF PRODUCT CHARACTERISTICS

7. Marketing Authorization Holder:

MICRO LABS LIMITED

31, Race course road

Bangalore-560001

INDIA

8.Marketing Authorization Numbers

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9.Date of first authorization

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10.Date of revision of text

Oct 2021