Ocurest® Plus
Eye Drops

1. Composition

Naphazoline Hydrochloride BP	0.1%w/v
Boric Acid BP	1.0%w/v
Menthol IP	0.0025%w/v
Camphor IP	0.0025%w/v
Hydroxypropyl Methylcellulose IP	0.2%w/v
Borax IP	0.05%w/v

2. Dosage form and strength

Ocurest plus New Eye Drops is available in 10ml vial.

3. Clinical particulars

3.1 Therapeutic indication

Ocurest plus New Eye Drops is indicated in allergic conjunctivitis and computer vision.

3.2 Posology and method of administration

As directed by physician.

3.3 Contraindication

The use of Ocurest plus New Eye Drops is contraindicated in patients with:

- Hypersensitivity to any of the ingredients of the formulation.
- Prescription of MAO inhibiting compound.

3.4 Special warnings and precautions for use

- If irritation persist or increases, consult physician.
- Caution is advised in patient with Closed-angle glaucoma, hypertension or cardiac disease, hyperthyroidism, diabetes mellitus and ocular infection or ocular trauma.
- Limit alcoholic beverages.

3.5 Drug interactions

There are no drug interactions associated with Ocurest plus New Eye Drops.

3.6 Use in special population

- Paediatric: Use with caution.
- Geriatric: Use with caution.
- Liver impairment: There is no data available. Doctor consultation is advised.
- Renal failure: Caution to be advised in patients with severe impaired renal function.
- Pregnancy and lactation: Naphazoline is classified as FDA pregnancy category C. It is not known if the drug can cause fetal harm when administered to a pregnant woman. Limited data have not demonstrated a clinically significant effect on the foetus during first trimester exposure of naphazoline; however, other sympathomimetic drugs have been associated with minor malformations, inguinal hernia, and clubfoot. Ocurest plus New Eye Drops should be given to a pregnant woman only if clearly needed.

  It is not known whether Naphazoline passes into breast milk. Consultation doctor before breast-feeding is advised.

3.7 Effects on ability to drive and use machine

Patients should be cautioned against engaging in activities requiring complete mental alertness, and motor coordination such as operating machinery until their response to Ocurest plus New Eye Drops is known.

3.8 Undesirable effects

- Rebound congestion may occur after frequent or prolonged use.
- CNS depression with marked reduction of body temperature and bradycardia, sweating, drowsiness, and coma, particularly in children.
- Hypertension may be followed by rebound hypotension
- Keratitis, nausea, headache, and dizziness, diarrhoea, abdominal pain, an erythematous rash involving both skin and mucous membranes

3.9 Overdose

There is limited experience of overdose with Ocurest plus New Eye Drops. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

4. Pharmacological properties

4.1 Mechanism of action

Naphazoline is a direct acting sympathomimetic drug, which acts on alpha-adrenergic receptors in the arterioles of the nasal mucosa. This activates the adrenal system to yield

systemic vasoconstriction. In producing vasoconstriction, the result is a decrease in blood flow in the nasal passages and consequently decreased nasal congestion. The vasoconstriction means that there is less pressure in the capillaries and less water can filter out, thus less discharge is made.

Boric acid has weak bacteriostatic and fungistatic properties. It used to soothe, cleanse and refresh irritated eye.

Menthol primarily activates the cold-sensitive TRPM8 receptors in the skin. Menthol, after topical application, causes a feeling of coolness due to stimulation of 'cold' receptors by inhibiting Ca++ currents of neuronal membranes. It may also yield analgesic properties via kappa-opioid receptor agonism.

4.2 Pharmacodynamic properties

Naphazoline is a direct acting sympathomimetic adrenergic alpha-agonist used to induce systemic vasoconstriction, thereby decreasing nasal congestion and inducing constriction around the conjunctiva. The sympathomimetic action of Naphazoline constricts the smaller arterioles of the nasal passages, producing a decongesting effect. Naphazoline ophthalmic causes constriction of blood vessels in the eyes. It also decreases itching and irritation of the eyes. Naphazoline constricts the vascular system of the conjunctiva. It is presumed that this effect is due to direct stimulation action of the drug upon the alpha adrenergic receptors in the arterioles of the conjunctiva resulting in decreased conjunctival congestion. Naphazoline belongs to the imidazoline class of sympathomimetics.

Boric acid exhibits minimal bacteriostatic and antifungal activities. Boric acid is likely to mediate antifungal actions at high concentrations over prolonged exposures.

Menthol is a covalent organic compound made synthetically or obtained from peppermint or other mint oils. Menthol's ability to chemically trigger cold-sensitive receptors in the skin is responsible for the well-known cooling sensation that it provokes when inhaled, eaten, or applied to the skin. It should be noted that menthol does not cause an actual drop in temperature.

4.3 Pharmacokinetic properties

Systemic absorption has been reported after topical use of solutions of naphazoline. It is not given systemically, but it is readily absorbed from the gastrointestinal tract. Naphazoline instilled into the eye causes conjunctival vasoconstriction within 10 minutes and effects can last for up to 6 hours.

Boric acid is absorbed from the gastrointestinal tract, from damaged skin, from wounds, and from mucous membranes. It does not readily penetrate intact skin. About 50% of the

amount absorbed is excreted in the urine within 24 hours and most of the remainder is excreted within 96 hours of ingestion.

After absorption, menthol is excreted in the urine and bile as a glucuronide.

Camphor is readily absorbed from all administration sites. It is hydroxylated in the liver to yield hydroxy camphor metabolites which are then conjugated with glucuronic acid and excreted in the urine. Camphor crosses the placenta.

5. Nonclinical properties

5.1 Animal Toxicology or Pharmacology

Not required.

6. Description

Already mentioned and covered in the above points.

7. Pharmaceutical particulars

7.1 Incompatibilities

There are no known incompatibilities.

7.2 Shelf-life

24 months.

7.3 Storage and handling instructions

Store in dry, well ventilated place at temperature not exceeding 30^{o}C.