

#### 1. Generic Name

- Boric acid
- Sodium Borate IP
- Zinc Sulphate IP
- Glycerine
- Chlorbutol
- Camphor and Menthol

## 2. Qualitative and Quantitative composition

•	Boric acid IP	2.0% w/v
•	Sodium Borate IP	0.5% w/v
•	Zinc Sulphate IP	0.1% w/v
•	Glycerine IP	2% w/v
•	Chlorbutol IP	0.5% w/v

• (Camphor 0.01% + Menthol 0.01% in excipients)

## 3. Dosage form and strength

• Eye drops containing topical ophthalmic solution of Boric acid IP 2.0% w/v , Sodium Borate IP 0.5% w/v , Zinc Sulphate IP 0.1% w/v

## 4. Clinical particulars

### 4.1 Therapeutic indication

Indicated for treatment of ocular discomfort, and inflammation of a non-infectious origin.

## 4.2 Posology and method of administration

Instil 3-4 drops in affected eye 3 times a day or as directed by physician.

### 4.3 Contraindication

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

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

- 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.

## 4.4 Drug interactions

The use of OCUREST PLUS NEO eye drops is contraindicated in patients with a history of hypersensitivity to any of the components in this medication.

### 4.5 Use in special population

- Pediatric: Safety and efficacy in children has not been established.
- Geriatric: Safety and efficacy in geriatric patients has not been established.
- Liver impairment: There is no data available. Doctor consultation is advised.
- Renal failure: Caution to be advised in patients with severe impaired renalfunction.
- Pregnancy and lactation: There are no well-controlled trials with OCUREST PLUS NEO in pregnant and lactating women. Therefore OCUREST PLUS NEO eye drops should only be used if clearly indicated

## 4.6 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 Neo eye drop is known.

### 4.7 Undesirable effects

The common side effects are Eye irritation, Eye pain, Vision blurred.

#### 4.8 Overdose

There is limited experience of overdose with Ocurest Plus Neo eye drops. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

### 5. Pharmacological properties

#### 5.1 Mechanism of action

Boric acid and Sodium borate has anti-inflammatory and has mild bacteriostatic and fungistatic properties. It used to soothe, cleanse, and refresh irritated eye.

Zinc sulphate acts as an astringent

Glycerine prevents oxidative stress and prevent apoptosis rate of endothelial cells.

Menthol and camphor give cooling and soothing effect in eye.

### 5.2 Pharmacodynamic properties

Boric acid and Sodium borate exhibit 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.

### 5.3 Pharmacokinetic properties

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.

### 6. Nonclinical properties

### 6.1Animal Toxicology or Pharmacology

Not required.

# 7. Description

8.	Boric acid	Sodium borate	Zinc Sulphate
Activity	Anti-inflammatory, Anti- infective	Anti-inflammatory, Anti- infective	Astringent
Chemical name	-	-	-
Chemical Structure	H O H	NaO, B, O, B, O, O, O, B, O, O, O, O, D, O, O, D, O, O, D, O,	${}_{O}^{O} \geqslant S < {}_{O}^{O} \geqslant Zn$
Empirical formula	H <sub>3</sub> BO <sub>3</sub>	Na <sub>2</sub> [B <sub>4</sub> O₅(OH) <sub>4</sub> ]·8H <sub>2</sub> O	ZnSO4·7H2O
Molecular weight	61.83 g/mol	381.37 g/mol	161.47 g/mol

# 9. Pharmaceutical particulars

## 9.1 Incompatibilities

There are no known incompatibilities.

### 9.2 Shelf-life

24 months.

## 9.3 Packaging Information

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

## 9.4 Storage and handling instructions

Store in dry, well-ventilated place at temperature not exceeding 30°C.

## 10. Patient Counselling Information

### 9.1 Adverse reactions

Refer part 4.8

## 9.2 Drug Interactions

Refer part 4.8

### 9.3 Dosage

Refer part 4.5

## 9.4 Storage

Refer part 8.4

### 9.5 Risk factors

Refer part 4.4

## 9.6 Self-monitoring information

NA

## 9.7 Information on when to contact a health care provider or seek emergency help

Patient is advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing physician.

### 9.8 Contraindications

Refer part 4.3

## 10. Manufactured by Sayora Pharma Pvt.Ltd

## 11. Details of permission or license number with date

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