Ocurest®
NEW
Eye Drops

## 1. Generic Name

Boric acid
Borax
Zinc Sulphate
Menthol
BKC
Camphor

## 2. Qualitative and Quantitative composition

| | |
|---|---|
| Boric acid IP | 2.0% w/v |
| Borax IP | 0.2% w/v |
| Zinc Sulphate IP | 0.0004% w/v |
| Menthol IP | 0.005% w/v |
| BKC IP | 0.004% v/v |
| Camphor | 0.01% w/v |

## 3. Dosage form and strength

Eye drops containing topical ophthalmic solution of Boric acid 2% w/v, Borax 0.2% w/v and Zinc Sulphate 0.0004% w/v.

## 4. Clinical particulars

### 4.1 Therapeutic indication

In patients of ocular redness and inflammation of a non-infectious origin.

### 4.2 Posology and method of administration

One or two drops four times a day.

### 4.3 Contraindication

The use of OCUREST New is contraindicated in patients with a history of hypersensitivity to any of the components in this medication.

**4.4 Special warnings and precautions for use**

The use of OCUREST New should be discontinued If patient experiences pain, changes in vision, continued redness or irritation, or if the condition worsens, or persists for more than 72 hours.

**4.5 Drug interactions**

Drug-drug interaction studies have not been conducted with Boric acid 2% w/v, Borax 0.2% w/v and Zinc Sulphate 0.0004% w/v ophthalmic solution.

**4.6 Use in special population**

**Pediatric:** Safety and efficacy in children has not been established.

**Geriatric:** Safety and efficacy in elderly has not been established.

**Liver impairment:** There is no data available

**Renal failure:** Caution to be advised in patients with severe impaired renal function.

**Pregnancy and lactation:** There are no well-controlled trials with OCUREST New in pregnant and lactating women. Therefore, OCUREST New should only be used if clearly indicated.

**4.7 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 New is known.

**4.8 Undesirable effects**

The common side effects include Eye irritation, Eye pain, Mydriasis, Periorbital edema, Ocular hyperemia, Vision blurred.

**4.9 Overdose**

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

**5. Pharmacological properties**

**5.1 Mechanism of action**

Boric acid, a mild water-soluble acid, is used to rinse the eyes to help relieve the discomfort of pink eye or viral eye infections. It can be applied in the form of drops in the affected eye to relieve discomfort. Boric acid also acts as a buffering agent to stabilize the pH of the formulation.

Both boric acid and borax have shown to have anti-inflammatory and mild anti-infective activity against fungus and bacteria.

Zinc sulphate acts as a mild astringent which helps reduce eye discharge. It also acts a preservative

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.

Camphor provides cooling and soothing effect.

**5.2 Pharmacodynamic properties**

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

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 readily absorbed from the gastrointestinal tract in rats and humans. At least 92% of a single oral dose of boric acid was recovered in the urine of human volunteers. It is also distributed in body fluids. Metabolism of inorganic borates by biological systems is not feasible owing to the excessive energy required to break the boron-oxygen bond (523 kJ/mol). Boric acid clearance is similar in animals and humans. Over 90% of the dose administered is excreted in the urine, independently of the administration route. The maximum elimination half-life is 24 hours.

Zinc is incompletely absorbed from the small bowel, with between 10 and 40% of an ingested dose absorbed. Numerous dietary components can interfere with zinc absorption, particularly phytates and fibre, which bind to zinc, resulting in poorly absorbed zinc complexes. Approximately 60% of circulating zinc is bound to albumin and roughly 30% is boundto macroglobulin. The majority of zinc is stored in the liver and kidney, chiefly intracellularly, and bound to metalloproteins. In adults, it has been estimated that 0.5–1 mg is secreted daily in the biliary tract and excreted in the stool, while 0.5–0.8 mg is excreted daily in the urine.

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.

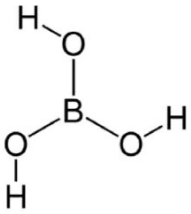
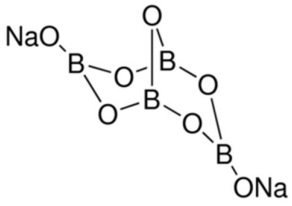
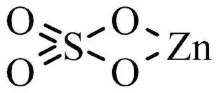
After absorption, menthol is excreted in the urine and bile as a glucuronide. The systemic absorption of camphor, menthol, and methyl salicylate from dermal patches containing all three ingredients has been studied. The absolute bioavailability of these compounds could not be determined from this study, but there did not appear to be any substantial systemic accumulation even after unrealistically high exposure for prolonged periods.

## 6. Nonclinical properties

### 6.1 Animal Toxicology or Pharmacology

Not required.

## 7. Description

| | **Boric acid** | **Borax** | **Zinc Sulphate** |
|---|---|---|---|
| **Activity** | Anti-inflammatory, Anti-infective | Anti-inflammatory, Anti-infective | Astringent |
| **Chemical name** | - | - | - |
| **Chemical Structure** |  |  |  |
| **Empirical formula** | $H_3BO_3$ | $Na_2[B_4O_5(OH)_4]\cdot 8H_2O$ | ZnSO4·7H2O |
| **Molecular weight** | 61.83 g/mol | 381.37 g/mol | 161.47 g/mol |

## 8. Pharmaceutical particulars

### 8.1 Incompatibilities

There are no known incompatibilities.

**8.2 Shelf-life**

24 months

**8.3 Packaging Information**

OCUREST New is available in a 10 ml lupolen vial

**8.4 Storage and handling instructions**

Store in cool and dry place.

**9. 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. Details of Manufacturer: Sayora Pharma Pvt.Ltd.**

**11. Details of Permission or license number with date** LIC.NO.G/28/1536, 11.10.2019

**12. Date of revision: April 2025**