Ocurest®-AH

NEW
Eye Drops

1.Generic Name

Chlorpheniramine

Phenylephrine

Boric acid

HPMC

BKC

Menthol

Camphor

2.Qualitative and Quantitative composition

Chlorpheniramine	0.2%w/v
Phenylephrine hydrochloride	0.12% w/v
Boric acid	1.25% w/v
HPMC	0.3% w/v
BKC	0.01% w/v
Menthol	0.01% w/v
Camphor	0.01% w/v

3.Dosage form and strength

Eye drops containing topical ophthalmic solution of containing Chlorpheniramine 0.2%, Phenylephrine hydrochloride 0.12% and Boric acid 1.25%.

4.Clinical particulars

4.1Therapeutic indication

In patients of ocular allergy and inflammation due to allergy.

4.2 Posology and method of administration

One or two drops four times a day.

4.3 Contraindication

The use of OCUREST AH NEW EYE DROPS is contraindicated in patients with narrow angle glaucoma.

4.4 Special warnings and precautions for use

- The use of OCUREST AH NEW EYE DROPS should be with caution in patients with heart disease, hypertension or difficulty in urination due to enlargement of the prostate gland.
- Prolonged use of decongestants is associated with rebound congestion.
- The use of OCUREST AH NEW EYE DROPS 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.
- It is advisable not to drive, operate machinery or perform other hazardous activities when on treatment with OCUREST AH NEWNEW EYE DROPS.

Drug interactions

Although, clinically significant drug-drug interactions between OCUREST AH NEW EYE DROPS and systemically administered drugs are not expected but may occur when co administered with monoamine oxidase inhibitors or beta blockers.

5 Use in special population

- Pediatric: Safety and efficacy in children has not been established.
- Geriatric: Safety and efficacy in elderly patients 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 AH NEW EYE DROPS in pregnant and lactating women. Therefore, OCUREST AH NEW EYE DROPS should only be used if clearly indicated.

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 AH New is known.

7 Undesirable effects

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

8 Overdose

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

1. Pharmacological properties

5.1 Mechanism of action

In allergic reactions, an allergen interacts with and cross-links surface IgE antibodies on mast cells and basophils. Once the mast cell-antibody-antigen complex is formed, a complex series of events occurs that eventually leads to cell-degranulation and the release of histamine (and other chemical mediators) from the mast cell or basophil. Once released, histamine can react with local or widespread tissues through histamine receptors. Histamine, acting on H1-receptors, produces pruritis, vasodilatation, hypotension, flushing, headache, tachycardia, and bronchoconstriction. Histamine also increases vascular permeability and potentiates pain. Chlorpheniramine maleate binds to the histamine H1 receptor. This blocks the action of endogenous histamine, which subsequently leads to temporary relief of the negative symptoms brought on by histamine.

Phenylephrine hydrochloride is an α-1 adrenergic agonist drug that is used in ophthalmology mainly for its mydriatic effect. After topical application to the conjunctiva, phenylephrine acts directly on α-adrenergic receptors in the eye, producing contraction of the dilator muscle of the pupil and constriction of the arterioles in the conjunctiva.

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

Chlorpheniramine maleate is a histamine H1 antagonist of the alkyl amine class. It competes with histamine for the normal H1-receptor sites on effector cells of the gastrointestinal tract, blood vessels and respiratory tract. It provides effective, temporary relief of sneezing, watery and itchy eyes, and runny nose due to hay fever and other upper respiratory allergies.

Phenylephrine is a powerful vasoconstrictor. It is used as a nasal decongestant and cardiotonic agent. Phenylephrine is a postsynaptic α1-receptor agonist with little effect on β-receptors of the heart. Parenteral administration of phenylephrine causes a rise in systolic and diastolic pressures, a slight decrease in cardiac output, and a considerable increase in peripheral resistance; most vascular beds are constricted, and renal, splanchnic, cutaneous,

and limb blood flows are reduced while coronary blood flow is increased. Phenylephrine also causes pulmonary vessel constriction and subsequent increase in pulmonary arterial pressure. Vasoconstriction in the mucosa of the respiratory tract leads to decreased edema and increased drainage of sinus cavities.

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

Chlorpheniramine maleate is absorbed relatively slowly from the gastrointestinal tract, peak plasma concentrations occurring about 2.5 to 6 hours after oral doses. Bioavailability is low, values of 25 to 50% having been reported. Chlorpheniramine appears to undergo considerable first-pass metabolism. About 70% of Chlorpheniramine in the circulation is bound to plasma proteins. There is wide inter individual variation in the pharmacokinetics of Chlorpheniramine; values ranging from 2 to 43 hours have been reported for the half-life. Chlorpheniramine is widely distributed in the body, and enters the CNS. Chlorpheniramine maleate is extensively metabolised. Metabolites include desmethyl- and didesmethyl Chlorpheniramine. Unchanged drug and metabolites are excreted primarily in the urine; excretion is dependent on urinary pH and flow rate. Only trace amounts have been found in the faeces. Duration of action of 4 to 6 hours has been reported; this is shorter than may be predicted from pharmacokinetic parameters. More rapid and extensive absorption, faster clearance, and a shorter half-life have been reported in children.

Phenylephrine has low oral bioavailability owing to irregular absorption and first-pass metabolism by monoamine oxidase in the gut and liver. When injected subcutaneously or intramuscularly it takes 10 to 15 minutes to act; subcutaneous and intramuscular injections are effective for up to about 1 hour and up to about 2 hours, respectively. Intravenous injections are effective for about 20 minutes. Systemic absorption follows topical application.

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.

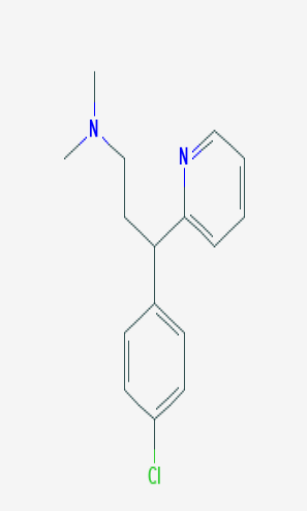
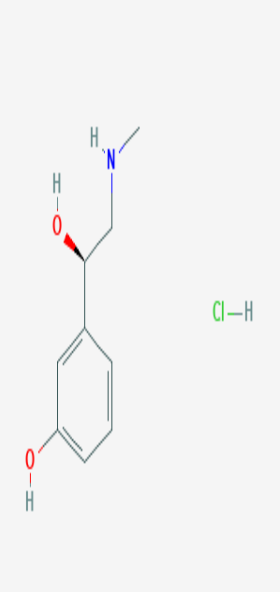
After absorption, menthol is excreted in the urine and bile as a glucuronide. The systemic absorption of camphor, menthol, and methyl salicylate from dermal patches containing all three ingredients has been studied. The absolute bioavailability of these compounds could not be determined from this study,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

6.Nonclinical properties

6.1Animal Toxicology or Pharmacology

N.A

7. Description

	Chlorpheniramine	**Phenylephrine hydrochloride**
Class	First generation antihistamines	Direct acting sympathomimetic amine (Decongestant)
Chemical name	3-(4-chlorophenyl)-*N*,*N*-dimethyl-3-pyridin-2-ylpropan-1-amine	3-[(1*R*)-1-hydroxy-2-(methylamino) ethyl]phenol; hydrochloride
Structural formula		
Empirical formula	$C_{16}H_{19}ClN_2$	$C_9H_{14}ClNO_2$
Molecular weight	274.79 g/mol	203.66 g/mol

8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

24 months**.**

8.3 Packaging Information

OCUREST AH NEW EYE DROPS 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. Manufactured by SAYORA PHARMACEUTICALS PVT.LTD

11. Details of permission or license number with date 599-B(H) 01/04/2022

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