110 mm

200 mm

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

BRIMONIDINE TARTRATE OPHTHALMIC SOLUTION (0.15%) 1.5 mg/ml

BRIMOGAN

Composition:

Each mL contains:
Brimonidine Tartrate Ph.Eur. ...1.5 mg
Preservative: Benzalkonium
chloride.....0.005%

Inactives:
Citric Acid Monohydrate, Polyvinyl Alchol,
Sodium Chloride, Sodium Citrate, Water for
Injection, Hydrochloric acid and/or Sodium
Hydroxide may be added to adjust pH.

Product description: Clear, greenish-yellow solution, free from any particulate matter

PHARMACOLOGY

Pharmacodynamics

Brimonidine is an alpha adrenergic receptor agonist. It has a peak ocular hypotensive effect occurring at two hours post dosing. Fluorophotometric studies in animals and humans suggest that brimonidine tartrate has a dual mechanism of action by reducing aqueous humor production and increasing uveoscleral outflow.

Pharmacokinetics

After ocular administration of a 1.5 mg/ml solution, plasma concentrations peaked within 1 to 4 hours and declined with a systemic half-life of approximately 3 hours. In humans, systemic metabolism of brimonidine is extensive. It is metabolized primarily by the liver. Urinary excretion is the major route of elimination of the drug and its metabolites. Approximately 87% of an orally administered radioactive dose was eliminated within 120 hours, with 74% found in the urine.

INDICATIONS

BRIMOGAN is indicated for lowering intraocular pressure in patients with open angle glaucoma or ocular hypertension.

CONTRAINDICATIONS

Brimonidine is contraindicated in patients with hypersensitivity to brimonidine tartrate or any component of this medication. It is also contraindicated in patients receiving monoamine oxidase (MAO) inhibitor therapy.

Contraindicated in neonates and infants (children under the age of 2 years)

WARNINGS AND PRECAUTIONS

Children of 2 years of age and above, especially those in the 2-7 age range and/or weighing ≤ 20 Kg, should be treated with caution and closely monitored due to the high incidence and severity of somnolence. Caution should be exercised in treating patients with severe or unstable and uncontrolled cardiovascular disease. Some patients have been reported an ocular allergic type reaction with Brimonidine. If allergic reactions are observed, treatment with Brimonidine should be discontinued. Delayed ocular hypersensitivity reactions have been reported with Brimogan, with some reported to be associated with an increase in IOP. Brimonidine should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension or thromboangiitis obliterans. Brimonidine has not been studied in patients with hepatic or renal impairment; caution should be used in treating such patients. The preservative in Brimonidine, benzalkonium chloride, may cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Known to discolour soft contact lenses.

Effects on ability to drive and use machines :

Brimonidine eye drops may cause fatigue and/or drowsiness which may impair the ability to drive or to use machinery. They may also blurred and/or abnormal vision, which may impair the ability to drive or to use machinery, especially at night or in reduced lighting. The patient should wait until these symptoms have cleared before driving or operating machinery.

Interaction with other Medicaments

Alphaagonists, as a class, may reduce pulse and blood pressure. Caution in using concomitant drugs such as betablockers (ophthalmic and systemic), antihypertensives and/or cardiac glycosides is advised. Tricyclic antidepressants have been reported to blunt the hypotensive effect of systemic clonidine. It is not known whether the concurrent use of these agents with Brimogan in humans can lead to resulting interference with the IOP lowering effect. Caution, however, is advised in patients taking tricyclic antidepressants which can affect the metabolism and uptake of circulating amines. No data on the level of circulating catecholamines after Brimogan administration are available.

Brimogan is contraindicated in patients receiving monoamine oxidase (MAO) inhibitor therapy and patients on antidepressants which affect noradrenagic transmission.

If more than one eye drops/ointment is to be used, the different medicines should be instilled at least 5 minutes apart.

Pregnancy

Teratogenic Effects: Pregnancy Category B.

Brimonidine should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the foetus.

Lactation

It is not known whether brimonidine is excreted in human milk, although in animal studies, Brimogan tartrate has been shown to be excreted in breast milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Paediatric Use

The safety and effectiveness have not been studied in paediatric patients below the age of 2 years. BRIMOGAN is not recommended for use in paediatric patients under the age of 2 years.

Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and other adult patients.

UNDESIRABLE EFFECTS

Side effects occurring are oral dryness, ocular hyperemia, burning and stinging, headache, blurring foreign body sensation, fatigue/drowsiness, conjunctival follicles, ocular allergic reactions and ocular pruritus.

The following adverse reactions can be reported rarely: lid crusting, conjunctival hemorrhage, abnormal taste. insomnia, conjunctival discharge, depression, hypertension, anxiety, palpitations/arrhythmias, nasal dryness and syncope.

Events occurring also included corneal staining/erosion, photophobia, eyelid erythema, ocular ache/pain, ocular dryness, tearing, upper respiratory symptoms, eyelid edema, conjunctival edema, dizziness, blepharitis, ocular irritation, gastrointestinal symptoms asthenia, conjunctival blanching, abnormal vision and muscular pain.

The following events have been identified during post-marketing use of BRIMOGAN in clinical practice. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. The events, which have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to BRIMOGAN or a combination of these factors, include: bradycardia; hypotension; iritis; miosis; skin reactions (including erythema, eyelid pruritus, rash, and vasodilation); and tachycardia.

Apnea, bradycardia, hypotension, hypothermia, hypotonia, and somnolence have been reported in infants receiving BRIMOGAN.

OVERDOSAGE

Accidental consumption in blood circulation

Adults: There are only few studies reporting the effect of High dose of Bromonidine in blood circulation ,which says that, accidental intake of Bromonidine shows decrease in blood pressure.

Decrease in blood pressure was observed when we stop taking or lower the dose of high blood pressure medicine.

Management of an oral overdose can be done by decreasing the sign & symptoms of a disease, by maintaining patient's airway passage.

Oral high dose of other α-2-agonists shows symptoms such as decrease blood pressure, weakness, vomiting, drowsiness, sedation, decrease heart rate, irregular heartbeat, disturbed vision, sleep disorder, muscle weakness, fever, disturbance in nerve cell activity in the brain & breathing problem.

Paediatric population

Patients showed symptoms such as depression, typically temporary coma or low level of consciousness, tiredness, sleepiness, muscle weakness, decrease heart rate, fever, whiteness, breathing problem especially during sleep, sometimes patience may require admission to critical medical care with intubation to maintain an open airway if needed.

DOSAGE AND ADMINISTRATION

The recommended dose is one drop of Brimonidine 0.15% in the affected eye (s) three times daily, approximately 8 hours apart.

SHELF LIFE

24 Months

After opening (In-use) : Use the solution within 28 days after opening the vial.

STORAGE AND HANDLING INSTRUCTIONS

Before opening : Store below 30°C. Protect from Light.

After opening (In-use) : Use the solution within 28 days after opening the vial and store below 30°C.

Route of administration: Ophthalmic

PACKAGING INFORMATION

Plastic vial of 5 ml.

Manufactured by:
INDOCO REMEDIES LTD.
L-32, 33, 34, Verna Industrial Area, Verna, Goa 403 722, INDIA.
Regd. Office: 166, C.S.T. Road, Mumbai 400 098, INDIA.

Name & address of Product Registration Holder:
Arms Pharma Sdn. Bhd. 22-1, Jalan PJU 5/20D,
The Strand, 47810 Kota Damansara, Selangor, Malaysia.

Date of revision : February 2023

XXXXXXX

5 mm

10 mm

5 mm

Pharma code

50 mm