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

Brimonidine Tartrate Eye Drops 0.15% w/v

IOBRIM 0.15% w/v

EYE DROPS

COMPOSITION:
Brimonidine Tartrate Ph. Eur .....0.15 % w/v
Benzalkonium Chloride Ph. Eur .....0.005% w/v
(As preservative)
Aqueous Buffered Vehicle..... q.s.

DOSAGE FORM
Dosage Form: Ophthalmic
Dosage Form Description: Eye Drops

PRODUCT DESCRIPTION
IOBRIM EYE DROPS (Brimonidine Tartrate Eye Drops 0.15% w/v) is a clear, greenish yellow 5 mL solution packed in 5 mL Low density Polyethylene (LDPE), High Impact Polystyrene (HIPS) into a carton along with pack insert.

PHARMACODYNAMICS
Mechanism of action:
IOBRIM is an alpha adrenergic receptor agonist. It has a peak ocular hypotensive effect occurring at two hours post-dosing.
Pharmacokinetics
After ocular administration of either a 0.1% or 0.2% solution, plasma concentrations peaked within 0.5 to 2.5 hours and declined with a systemic half-life of approximately 2 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.

INDICATION
IOBRIM is indicated for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

RECOMMENDED DOSE
The recommended dose is one drop of IOBRIM (brimonidine tartrate ophthalmic solution) 0.15% in the affected eye(s) three times daily, approximately 8 hours apart.
If more than one topical ophthalmic drug is to be used, the different drugs should be instilled at least 5 minutes apart.

ROUTE OF ADMINISTRATION
Ocular

CONTRAINDICATION
IOBRIM 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 and contraindicated in neonates and infants (children under the age of 2 years).

WARNING AND PRECAUTIONS
General:
Caution should be exercised in treating patients receiving IOBRIM with severe cardiovascular disease. IOBRIM has not been studied in patients with hepatic or renal impairment; caution should be used in treating such patients. IOBRIM should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension, or thromboangiitis obliterans. Patients prescribed IOP-lowering medication should be routinely monitored for IOP.

Information for Patients:
As with other drugs in this class, IOBRIM may cause fatigue and /or drowsiness in some patients. Patients who engage in hazardous activities should be cautioned of the potential for a decrease in mental alertness. IOBRIM may also cause blurred vision or visual disturbance in some patients. The patient should wait until these symptoms have cleared before driving or using machinery.

a) If irritation persists or increases, discontinue the use and consult the physician.
b) Do not touch the vial tip to any surface since this may contaminate the solution.

INTERACTIONS WITH OTHER MEDICAMENTS
The possibility of an additive or potentiating effect with CNS depressants (alcohol, barbiturates, opiates, sedatives, or anesthetics) should be considered. Alpha-agonists, as a class, may reduce pulse and blood pressure. Caution in using concomitant drugs such as beta-blockers (ophthalmic and systemic), anti-hypertensives 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 IOBRIM in humans can lead to resulting interference with the IOP lowering effect. No data on the level of circulating catecholamines after IOBRIM administration are available. Caution, however, is advised in patients taking tricyclic antidepressants which can affect the metabolism and uptake of circulating amines.

PREGNANCY AND LACTATION
Teratogenic effects: Pregnancy Category B.
IOBRIM should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

Nursing Mothers:
It is not known whether this drug is excreted in human 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.

SIDE EFFECTS
Side effects: allergic conjunctivitis, conjunctival hyperemia, and eye pruritus. Adverse events: burning sensation, conjunctival folliculosis, hypertension, oral dryness, and visual disturbance.

Events: allergic reaction, asthenia, blepharitis, bronchitis, conjunctival edema, conjunctival hemorrhage, conjunctivitis, cough, dizziness, dyspepsia, dyspnea, epiphora, eye discharge, eye dryness, eye irritation, eye pain, eyelid edema, eyelid erythema, flu syndrome, follicular conjunctivitis, foreign body sensation, headache, pharyngitis, photophobia, rash, rhinitis, sinus infection, sinusitis, stinging, superficial punctuate keratopathy, visual field defect, vitreous floaters, and worsened visual acuity.

The following adverse reactions reported: corneal erosion, insomnia, nasal dryness, somnolence, and taste perversion.

SYMPTOMS AND TREATMENT OF OVERDOSE
Ophthalmic overdose: In those cases received, the events reported have generally been those already listed as adverse reactions.
Systemic overdose resulting from accidental ingestion: There is very limited information regarding accidental ingestion of brimonidine in adults. The only adverse event reported to date was hypotension. Treatment of an oral overdose includes supportive and symptomatic therapy; a patient airway should be maintained.

Symptoms of brimonidine overdose such as apnea, bradycardia, coma, hypotension, hypothermia, hypotonia, lethargy, pallor, respiratory depression, and somnolence have been reported in neonates, infants, and children receiving IOBRIM as part of medical treatment of congenital glaucoma or by accidental oral ingestion.

EFFECT ON ABILITY TO DRIVE AND USE MACHINE
Brimonidine Tartrate Eye Drops may cause fatigue and/or drowsiness, which may impair the ability to drive or operate machinery. Brimonidine Tartrate Eye Drops may cause 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 using machinery.

INSTRUCTION FOR USE
1. Ensure hands are clean before use.
2. Tighten the cap on the nozzle. The spike in the cap will pierce the tip of the vial.
3. Dispense drops with gentle pressure. Replace the cap after every use.

As with any eye drops, to reduce possible systemic absorption, it is recommended that the lachrymal sac be compressed at the medial canthus (punctal occlusion) for one minute. This should be performed immediately following the instillation of each drop. This may result in a decrease of systemic side effects and an increase in local activity. To avoid contamination of the eye or eye drops do not allow the dropper tip to come into contact with any surface.

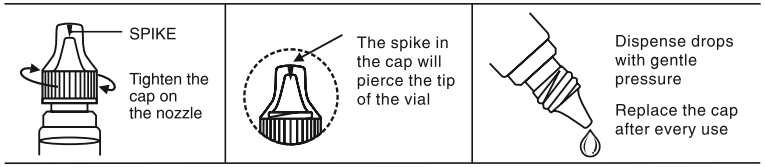
STORAGE CONDITION
Store below 30°C. Protect from light.

SHELF LIFE
Shelf Life Unopened : 24 Months
Shelf Life after first opening: 28 days

THERAPEUTICS CODE
ATC code : S01EA05

PRESENTATIONS
5 mL solution filled in 5 mL LDPE vial with HIPS cap. Labelled vial packed into a carton along with pack insert.

MODE OF USE



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FDC Limited	LEAFLET	Minipharma Code No.: **Front: 908/ Back: 262**
Size	110 (L) x 200 (H) mm	
Folded Size	----------	
No. of Folds	----------	
GSM	40 gsm	
Paper	Bible Paper	
Specification No.	---------	
Colour	■ TEXT IN BLACK	
Artwork Code: D1		Supercedes A/W Code: ----------
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