Brimopress® LS

Eye Drops

1. Composition

Brimonidine 0.1%w/v

2. Dosage form and strength

BRIMOPRESS-LS Ophthalmic Solution, 0.1% supplied in clear LDPE bottle with white cap in 5 ml size.

3. Clinical particulars

3.1 Therapeutic indication

BRIMOPRESS LS is indicated:

- In Timolol contraindicated patients.
- In treatment of primary open angle glaucoma and ocular hypertension.

3.2 Posology and method of administration

As directed by Physician.

3.3 Contraindication

BRIMOPRESS LS is contraindicated in:

- Neonates and Infants (under the age of 2 years)
- Hypersensitivity Reactions

3.4 Special warnings and precautions for use

- Potentiation of Vascular Insufficiency

BRIMOPRESS LS EYE DROPS may potentiate syndromes associated with vascular insufficiency. BRIMOPRESS LS EYE DROPS should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension, or thromboangiitis obliterans.

- Severe Cardiovascular Disease

Although Brimonidine tartrate ophthalmic solution had minimal effect on the blood pressure of patients in clinical studies, caution should be exercised in treating patients with severe cardiovascular disease.

- Contamination of Topical Ophthalmic Products After Use

There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers had been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface

- Use with Contact Lenses

The preservative in BRIMOPRESS LS EYE DROPS, benzalkonium chloride, may be absorbed by soft contact lenses. Patients wearing soft contact lenses should be instructed to wait at least 15 minutes after instilling BRIMOPRESS LS EYE DROPS to insert soft contact lenses.

3.5 Drug interactions

- Antihypertensives/Cardiac Glycosides

Because BRIMOPRESS LS EYE DROPS may reduce blood pressure, caution in using drugs such as antihypertensives and/or cardiac glycoside with BRIMOPRESS LS EYE DROPS is advised.

- CNS Depressants

Although specific drug interaction studies have not been conducted with BRIMOPRESS LS EYE DROPS, the possibility of an additive or potentiating effect with CNS depressants (alcohol, barbiturates, opiates, sedatives, or anesthetics) should be considered.

- Tricyclic Antidepressants

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 BRIMOPRESS LS EYE DROPS in humans can lead to resulting interference with the IOP lowering effect. Caution is advised in patients taking tricyclic antidepressants which can affect the metabolism and uptake of circulating amines.

- Monoamine Oxidase Inhibitors

Monoamine oxidase (MAO) inhibitors may theoretically interfere with the metabolism of Brimonidine and potentially result in an increased systemic side-effect such as hypotension. Caution is advised in patients taking MAO inhibitors which can affect the metabolism and uptake of circulating amines.

3.6 Use in special population

- Paediatric: BRIMOPRESS LS EYE DROPS is contraindicated in children under the age of 2 years.
- Geriatric: No overall differences in safety or effectiveness have been observed between elderly and other adult patients.
- Liver impairment: BRIMOPRESS LS EYE DROPS has not been studied in patients with hepatic impairment.
- Renal failure: BRIMOPRESS LS EYE DROPS has not been studied in patients with renal impairment. The effect of dialysis on Brimonidine pharmacokinetics in patients with renal failure is not known.
- Pregnancy and lactation: Pregnancy Category B: Teratogenicity studies have been performed in animals. There are no adequate and well-controlled studies in pregnant women; however, in animal studies, Brimonidine crossed the placenta and entered into the fetal circulation to a limited extent. Because animal reproduction studies are not always predictive of human response, BRIMOPRESS LS EYE DROPS should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

  It is not known whether Brimonidine tartrate is excreted in human milk, although in animal studies, Brimonidine tartrate has been shown to be excreted in breast milk. Because of the potential for serious adverse reactions from BRIMOPRESS LS EYE DROPS in nursing infants, 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.

3.7 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 BRIMOPRESS LS is known.

3.8 Undesirable effects

Most common adverse reactions occurring in approximately 10 to 30% of patients receiving Brimonidine ophthalmic solution 0.1% included oral dryness, ocular hyperaemia, burning and stinging, headache, blurring, foreign body sensation, fatigue/drowsiness, conjunctival follicles, ocular allergic reactions, and ocular pruritus.

3.9 Overdose

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

4. Pharmacological properties

4.1 Mechanism of action

BRIMOPRESS LS EYE DROPS is a relatively selective alpha-2 adrenergic receptor agonist with a peak ocular hypotensive effect occurring at two hours post-dosing. Fluor photometric studies in animals and humans suggest that Brimonidine tartrate has a dual mechanism of action by reducing aqueous humor production and increasing Uveosceleral outflow.

4.2 Pharmacodynamic properties

Not available.

4.3 Pharmacokinetic properties

After ocular administration of a 0.1% solution, plasma concentrations peaked within 1 to 4 hours and declined with a systemic half-life of approximately 3 hours. The protein binding of Brimonidine has not been studied. In humans brimonidine is extensively metabolized by the liver. Urinary excretion is the major route of elimination of brimonidine and its metabolites. Approximately 87% of an orally-administered radioactive dose of brimonidine was eliminated within 120 hours, with 74% found in the urine

5. Nonclinical properties

5.1 Animal Toxicology or Pharmacology

Not required.

6. Description

Already mentioned and covered in the above points.

7. Pharmaceutical particulars

7.1 Incompatibilities

There are no known incompatibilities.

7.2 Shelf-life

24 months.

7.3 Storage and handling instructions

Store below 30 C, protect from light. Do not freeze. Keep out of reach of children