LEVOPTIC EYE DROPS

(Levobunolol HCl 0.5% w/v)

COMPOSITION

Each mL contains Levobunolol Hydrochloride 5 mg (0.5% w/v). Excipients: according to the approved formulation.

DESCRIPTION

Levoptic is a sterile ophthalmic preparation containing levobunolol hydrochloride, a nonselective beta-adrenergic receptor blocking agent.

CLINICAL PHARMACOLOGY

Levobunolol lowers intraocular pressure (IOP), principally by reducing aqueous humour production. The effect may begin within 1 hour, peak in 2-6 hours and persist for up to 24 hours. It has little or no effect on pupil size or accommodation. Systemic absorption may produce beta-blocking effects.

INDICATIONS

Reduction of elevated intraocular pressure in patients with chronic open-angle glaucoma or ocular hypertension.

DOSAGE AND ADMINISTRATION

Initially instil 1-2 drops of 0.5% solution into the affected eye(s) once daily, or as directed by the ophthalmologist. In severe or uncontrolled glaucoma it may be used twice daily. Doses beyond one drop twice daily generally do not add benefit. Monitor IOP regularly. Additional antiglaucoma therapy may be prescribed if required.

METHOD OF ADMINISTRATION

For ophthalmic use only. Wash hands; do not touch the dropper tip to the eye or any surface. Close bottle promptly after use. If more than one ophthalmic medicine is used, separate instillations as advised by the physician.

CONTRAINDICATIONS

Hypersensitivity to levobunolol or a formulation component; bronchial asthma or a history of asthma; severe chronic obstructive pulmonary disease; sinus bradycardia; second- or third-degree atrioventricular block; overt cardiac failure; or cardiogenic shock.

WARNINGS

Topically administered levobunolol can be absorbed systemically. Serious respiratory and cardiovascular reactions, including bronchospasm, bradycardia, hypotension and cardiac failure, may occur. Patients with asthma or serious conduction disorders must not use it. Seek urgent medical attention if severe wheezing, difficulty breathing, fainting or slow heartbeat occurs.

PRECAUTIONS

Use cautiously in patients with impaired cardiac or lung function, Raynaud phenomenon or other vascular insufficiency, cerebrovascular insufficiency, myasthenia gravis, diabetes or risk of hypoglycaemia. Beta blockers can mask hypoglycaemia and hyperthyroidism symptoms. Tell the anaesthetist before surgery. Do not abruptly alter therapy without medical advice.

CONTACT LENSES

Where the formulation contains benzalkonium chloride, remove soft contact lenses before using the drops and wait at least 15 minutes before reinsertion. Confirm preservative status on the approved pack.

CONTAMINATION PREVENTION

Do not allow dropper tip to touch any surface. Do not use if the solution appears discoloured or contaminated. Consult an ophthalmologist if ocular injury, infection or surgery occurs.

DRUG INTERACTIONS

Systemic or other ophthalmic beta blockers may increase beta blockade; routine simultaneous use of two topical beta blockers is not recommended. Caution with oral or intravenous calcium-channel blockers, digitalis, catecholamine-depleting agents (such as reserpine), and other drugs affecting heart rate or blood pressure. Epinephrine with an ophthalmic beta blocker may cause pupil dilation.

PREGNANCY

Adequate controlled studies in pregnant women are lacking. Use only when the potential benefit justifies the possible risk to the fetus, on medical advice.

LACTATION

Excretion of levobunolol in human milk is not established. Caution is advised during breastfeeding; the physician should assess the risks and benefits.

PEDIATRIC USE

Safety and effectiveness in pediatric patients have not been established.

GERIATRIC USE

Clinical experience has not shown overall differences in safety or efficacy between older and younger adults. Monitor heart rate, blood pressure and IOP as appropriate.

DRIVING AND MACHINERY

Transient eye discomfort or visual disturbance, dizziness or fatigue may affect the ability to drive or use machinery. Wait until vision is clear and any symptoms resolve.

MONITORING

Periodic intraocular-pressure review is necessary. Patients at cardiovascular or respiratory risk may require additional clinical monitoring.

ADVERSE REACTIONS

Ocular: transient burning or stinging, blepharoconjunctivitis, irritation, allergic ocular reactions and occasionally reduced corneal sensitivity. Other effects reported include headache, dizziness, lethargy, rash and itching. Systemic beta-blocker effects may include slowed heart rate, low blood pressure, fainting, bronchospasm, shortness of breath, heart block or cardiac failure. Seek urgent care for serious breathing or cardiac symptoms.

OVERDOSAGE

If excessive drops are instilled, flush the eye with clean water or normal saline. Accidental ingestion or systemic overdose may cause bradycardia, hypotension, bronchospasm, heart block or cardiac failure. Obtain emergency medical assistance immediately. Treatment is supportive and directed by a healthcare professional.

STORAGE CONDITIONS

Store as specified on the approved product label. Protect from light and keep bottle tightly closed. Keep out of the reach of children. Do not use beyond the expiry date.

PRESENTATION

LEVOPTIC EYE DROPS: Levobunolol HCl 0.5% w/v sterile ophthalmic solution; 5 mL bottle.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.