Vegatrav Eye drops

Travoprost 0.004% w/v

Timolol (as timolol maleate) 0.5% w/v

Sterile Ophthalmic Solution

ویگاٹریو

(ٹریوپروسٹ + ٹموولول میلیٹ ایٹ)

DESCRIPTION:
Vegatrav sterile ophthalmic solution contains travoprost, a prostaglandin analogue, and timolol, a non-selective beta-adrenergic receptor blocking agent (beta-blocker) and Benzalkonium Chloride (as preservative).

COMPOSITION:
Each ml contains Travoprost USP 40 micrograms and Timolol Maleate USP eq. to Timolol 5.0mg.

INDICATIONS:
Vegatrav sterile ophthalmic solution is indicated for the decrease of intraocular pressure (IOP) in adult patients with open angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta blockers or prostaglandin analogues..

PHARMACOKINETICS PROPERTIES:
Pharmacodynamics (PD) In addition to reducing IOP, travoprost has been shown to increase optic nerve head blood flow based on data in rabbits following 7 days of topical ocular administration (1.4 micrograms, once daily).
Pharmacokinetics (PK)
Absorption: Travoprost and timolol are absorbed through the cornea. Travoprost is an isopropyl ester prodrug which undergoes rapid hydrolysis in the cornea to produce the active free acid Following once-daily administration of Vegatrav eye drops (polyquaternium-1-preserved) to healthy subjects for 5 days, travoprost free acid plasma concentrations were below the 0.010 ng/ml assay quantitation limit in the majority of samples. Quantifiable free acid concentrations were observable in some cases within 1-hour post-dose, ranging from 0,010 to 0,030 ng/mL The mean timolol steady-state C max was 1,34ng/mL and T max was approximately 0,69 hours after once-daily administration of Vegatrav eye drops. Timolol has a plasma elimination half-life of about 4 hours.

Distribution:
Travoprost free acid can be measured in the aqueous humor for several hours in animals and in human plasma up to 1-hour post-dose. Timolol can be measured in human aqueous humor after topical ocular administration of timolol and in plasma for up to 12 hours following topical ocular administration of Vegatrav eye drops.

Biotransformation/Metabolism:
Metabolism is the primary clearance mechanism for both Travoprost and its free acid. The systemic metabolic pathways for Travoprost free acid parallel those of endogenous prostaglandin F2à, which are characterized by reduction of the 13 to14 double bond, oxidation of the 15-hydroxyl to form a ketone and beta-oxidative cleavages of the carboxylic acid side chain. Timolol is primarily metabolized by CYP2D6 via two pathways. One route yields an ethanolamine side chain on the thiadiazol ring and the other generates an ethanolamine side chain an ethanolic side chain on the morpholine nitrogen side chain with a carbonyl function adjacent to the nitrogen. CYP2C19 was found to play a minor role in timolol metabolism.

Elimination:
Both Travoprost free acid and timolol, along with their respective metabolites, are primarily excreted in urine. Less than 2 % of an ocular dose of Travoprost was recovered in urine as Travoprost free acid. Approximately 20 % of a Timolol dose was found in urine as parent drug with the remainder excreted as metabolites. Due to the very low concentrations and rapid disappearance of Travoprost free acid from plasma, elimination half-life could not be determined. Timolol has a plasma elimination half-life of about 4 hours.

CONTRAINDICATIONS:
Hypersensitivity to the active substances or to any of the excipients. including Sinus bradycardia, sick sinus syndrome (including Sino-atrial block), second or third-degree atrioventricular block, overt cardiac failure, or cardiogenic shock.

WARNINGS AND PRECAUTIONS:
General: Like other topically applied ophthalmic agents, Travoprost and Timolol are absorbed systemically. Due to the beta-adrenergic blocking component in ophthalmic Timolol, the same types of cardiovascular, pulmonary and other adverse reactions seen with systemic beta-adrenergic blocking agents may occur.

Cardiac disorders: Rarely deaths in association with cardiac failure have been reported following systemic or ophthalmic administration of Timolol maleate. In patients with cardiovascular diseases (e.g., coronary heart disease,)
Vascular disorders: Patients with severe peripheral circulatory disturbance/disorders (ie, severe forms of Raynaud's disease or Raynaud's syndrome) should be treated with caution.
Respiratory disorders: Respiratory reactions, including death due to bronchospasm in patients with asthma have been reported following administration of some ophthalmic beta-blockers.
Hypoglycaemia/diabetes: Beta-blockers should be administered with caution in patients subject to spontaneous hypoglycemia or to patients with labile diabetes who are receiving insulin or oral hypoglycemic agents, as beta-blockers may mask the signs and symptoms of acute hypoglycemia.
Hyperthyroidism: Beta-blockers may mask the signs of hyperthyroidism.
Skin contact: Prostaglandins and prostaglandin analogues are biologically active substances that may be absorbed through the skin. Women who are pregnant or attempting to become pregnant should exercise appropriate precautions to avoid direct exposure to the contents of the bottle.
Anaphylactic reactions: While taking beta-blockers, patients with history of atopy or a history of severe anaphylactic reaction to a variety of allergens may be more reactive to repeated challenge with such allergens and unresponsive to the usual dose of adrenaline (epinephrine) used to treat anaphylactic reactions.
Ocular effects: Travoprost may gradually change the eye color by increasing the number of melanosomes (pigment granules) in melanocytes. Before treatment is instituted patients must be informed of the possibility of a permanent change in eye color. The change in iris color occurs slowly and may not be noticeable for months to years. Choroidal detachment: Choroidal detachment has been reported with administration of aqueous suppressant therapy (e.g. Timolol, acetazolamide) after filtration procedures.
Surgical anesthesia: Beta-blocking ophthalmological preparations may block systemic beta-agonist effects e.g. of adrenaline.

PREGNANCY & LACTATION:
Vegatrav eye drops should not be used in pregnancy. However, Vegatrav eye drop is administered during pregnancy up to time of delivery neonates should be monitored carefully.

PEDIATRIC PATIENTS (BELOW 18 YEARS)
The use of Vegatrav eye drops in pediatric patients is currently not recommended. The safety and efficacy of the use of Vegatrav eye drops in children and adolescents below the age of 18 years have not been established. No data is available.

GERIATRIC PATIENTS (65 YEARS OF 'AGE AND ABOVE)
No overall differences in safety or effectiveness have been observed between elderly and other adult patients.

DOSAGE:
The recommended dosage of Vegatrav is one drop in the conjunctival sac of the affected eye(s) once daily, in the morning or evening. It should be administered at the same time each day.
The dosage of Vegatrav eye drops should not exceed one drop in the affected eye(s) once daily since it has been shown that more frequent administration of prostaglandin analogues may decrease the IOP lowering effect.
If a dose is missed, treatment should be continued with the next dose as normal. If more than one topical ophthalmic drug is being used, the drugs should be administered at least 5 minutes apart.
When substituting another ophthalmic antiglaucoma medicinal product with Vegatrav eye drops, the other medicinal product should be discontinued, and Vegatrav eye drops should be started the following day.

PRESENTATION:
Vegatrav sterile ophthalmic solution 2.5mL is available in plastic dropper bottle.

INSTRUCTIONS:
Store below 30° C.
Protect from heat and sunlight.
Keep out of the reach of children.
Use within four weeks after first opening the bottle.
To be sold on the prescription of registered medical practitioner only.

مقدار اور طریقہ استعمال:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:
۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی اور دھوپ سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
پہلی مرتبہ بوتل کھولنے کے بعد دوا کو چار ہفتوں تک استعمال کیا جا سکتا ہے۔
صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔

VEGA

Manufactured by:
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