NOVARTIS

IZBA (travoprost)

30 micrograms/ml eye drops, solution

Basic Succinct Statement

CODE: BSS 75761-0; APPR 08 FEB 18

This material is only meant for Healthcare Professionals

IZBA

Important note: Before prescribing, consult full prescribing information.

Presentation: Plastic bottle with dispensing plug and closure, containing 2.5 ml, presented in an overwrap. 1 ml of solution contains 30 micrograms of travoprost. Preservative: 1 ml of solution contains 10 micrograms of polyquaternium-1. Excipients with known effect : 1 ml of solution contains 7.5 mg propylene glycol and 2 mg polyoxyethylene hydrogenated castor oil 40 (HCO-40)

Indications: IZBA eye drops contains travoprost, a prostaglandin analogue. IZBA eye drops is indicated for the decrease of elevated intraocular pressure in adult patients with ocular hypertension or open-angle glaucoma.

Dosage and administration: ♦**Use in adults (including elderly):** The dose is 1 drop of IZBA eye drops in the conjunctival sac of the affected eye(s) once daily. Optimal effect is obtained if the dose is administered in the evening. If a dose is missed, treatment should be continued with the next dose as planned. The dose should not exceed 1 drop in the affected eye(s) daily. When substituting another ophthalmic antiglaucoma medicinal product with IZBA eye drops, the other medicinal product should be discontinued and IZBA eye drops should be started the following day. ♦**Use in patients with hepatic or renal impairment:** Travoprost 30 μg / ml has not been studied in patients with hepatic or renal impairment. However, travoprost 40 μg / ml has been studied in patients with mild to severe hepatic impairment and in patients with mild to severe renal impairment (creatinine clearance as low as 14 ml / min). No dosage adjustment is necessary in these patients. Therefore, no need for dose adjustment at the lower concentration of active ingredient is anticipated. ♦**Use in children and adolescents:** The safety and efficacy of IZBA eye drops in children and adolescents below the age of 18 years has not been established. No data are available. ♦**For ocular use.** For patients who wear contact lenses, patients must be instructed to remove contact lenses prior to application of IZBA eye drops and wait at least 15 minutes after instillation of the dose before reinsertion. The patient should remove the protective overwrap immediately prior to initial use. To prevent contamination of the dropper tip and solution, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip of the bottle. Keep the bottle tightly closed when not in use. Nasolacrimal occlusion or gently closing the eyelid after administration is recommended. This may reduce the systemic absorption of medicinal products administered via the ocular route and result in a decrease in systemic adverse reactions. If more than one topical ophthalmic medicinal product is being used, the medicinal products must be administered at least 5 minutes apart. Eye ointments should be administered last.

Contraindications: ♦Hypersensitivity to the active substance or to any of the excipients in this product.

Warnings and Precautions: ♦**Eye colour change:** Travoprost may gradually change the eye colour 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 colour. Unilateral treatment can result in permanent heterochromia. The long term effects on the melanocytes and any consequences thereof are currently unknown. The change in iris colour occurs slowly and may not be noticeable for months to years. The change in eye colour has predominantly been seen in patients with mixed coloured irides, i.e., blue-brown, grey-brown, yellow-brown and green-brown; however, it has also been observed in

patients with brown eyes. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery in affected eyes, but the entire iris or parts of it may be become more brownish. After discontinuation of therapy, no further increase in brown iris pigment has been observed. ♦**Periorbital and eye lid changes:** In controlled clinical trials, periorbital and / or eyelid skin darkening in association with the use of travoprost has been reported in 0.2 % of patients. Periorbital and lid changes including deepening of the eyelid sulcus have been observed with prostaglandin analogues. Travoprost may gradually change eyelashes in the treated eye(s) ; these changes were observed in about half of the patients in clinical trials and include : increased length, thickness, pigmentation, and / or number of lashes. The mechanism of eyelash changes and their long term consequences are currently unknown. There is no experience of travoprost in inflammatory ocular conditions; nor in neovascular, angle-closure, narrow-angle or congenital glaucoma and only limited experience in thyroid eye disease, in open-angle glaucoma of pseudophakic patients and in pigmentary or pseudoexfoliative glaucoma. ♦**Aphakic patients:** Caution is recommended when using travoprost in aphakic patients, pseudophakic patients with a torn posterior lens capsule or anterior chamber lenses, or in patients with known risk factors for cystoid macular oedema. ♦**Iritis / uveitis:** In patients with known predisposing risk factors for iritis / uveitis, travoprost can be used with caution. ♦**Contact with the skin:** Skin contact with travoprost must be avoided as transdermal absorption of travoprost has been demonstrated in rabbits. Prostaglandins and prostaglandin analogues are biologically active materials 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. In the unlikely event of coming in contact with a substantial portion of the contents of the bottle, thoroughly cleanse the exposed area immediately. ♦**Excipients:** IZBA eye drops contains propylene glycol which may cause skin irritation. IZBA eye drops contains polyoxyethylene hydrogenated castor oil 40 which may cause skin reactions. ♦**Effects on ability to drive and use machines:** IZBA eye drops has no or negligible influence on the ability to drive and use machines. Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, the patient must wait until the vision clears before driving or using machines.

Adverse drug reactions: ♦**Summary of the safety profile:** In a clinical trial of 3 months duration (N = 442) involving IZBA eye drops as monotherapy, the most common adverse reaction observed was hyperaemia of the eye (ocular or conjunctival) reported in approximately 12 % of the patients. ♦**List of adverse reactions:** The following adverse reactions were assessed to be related with IZBA eye drops monotherapy and Travoprost 40 µg / ml eye drops, solution (either preserved with benzalkonium chloride or polyquaternium-1). They are classified according to the following convention : very common (≥1 / 10), common (≥1 / 100 to <1 / 10), uncommon (≥1 / 1,000 to <1 / 100), rare (≥1 / 10,000 to <1 / 1,000), very rare (<1 / 10,000) and not known (cannot be estimated from the available data). Within each frequency grouping, adverse reactions are presented in decreasing order of seriousness.

►Travoprost 30 µg / mL eye drops, solution (IZBA eye drops)

♦**Very common:** ocular hyperaemia; ♦**Common:** dry eye, eye pruritus, ocular discomfort; ♦**Uncommon:** punctate keratitis, anterior chamber inflammation, blepharitis, eye pain, photophobia, visual impairment, vision blurred, conjunctivitis, eyelid oedema, eyelid margin crusting, eye discharge, dark circles under eyes, growth of eyelashes, eyelash thickening, pruritus, rash.

►Travoprost 40 µg / ml eye drops, solution

♦**Very common:** ocular hyperaemia, iris hyperpigmentation; ♦**Common:** punctate keratitis, anterior chamber inflammation, eye pain, photophobia, eye discharge, ocular discomfort, visual acuity reduced, vision blurred, dry eye, eye pruritus, lacrimation increased, erythema of eyelid, eyelid oedema, growth of eyelashes, eyelash discolouration, skin hyperpigmentation (periocular), skin discolouration; ♦**Uncommon:** herpes simplex, keratitis herpetic, hypersensitivity, drug hypersensitivity, seasonal allergy, dysgeusia, dizziness, visual field defect, corneal erosion, uveitis, keratitis, eye inflammation, photopsia, blepharitis, conjunctival oedema, halo vision, conjunctivitis, conjunctival follicles, hypoaesthesia eye, meibomianitis, ectropion, anterior chamber pigmentation, mydriasis, cataract, eyelid margin crusting, asthenopia, heart rate irregular, palpitations, heart rate decreased, blood pressure decreased, blood pressure increased, hypotension, hypertension, dyspnoea, asthma, respiratory disorder, oropharyngeal pain, cough, dysphonia, nasal congestion, throat irritation, peptic ulcer reactivated, dry mouth gastrointestinal disorder, constipation, dermatitis allergic, periorbital oedema, dermatitis contact, erythema, rash, hair colour changes, hair texture abnormal, hypertrichosis, madarosis, musculoskeletal pain, asthenia, malaise; ♦**Not Known:** macular oedema, sunken eyes, vertigo, tinnitus, bradycardia, tachycardia, asthma aggravated, hair growth abnormal, prostatic specific antigen increased.