Summary of product characteristics

Xalatrex
Eye Drops

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1. Name of the medicinal product:
Xalatrex Eye drops.

2. Qualitative and quantitative composition:
Each 1ml contains:
Latanoprost ……..…. 50mg
For excipients see section 6.1

3. Pharmaceutical form:

Clear liquid filled in a tight light resistance plastic dropper bottle.

4. Clinical particulars:

4.1 Therapeutic indications:

Reduction of elevated intraocular pressure in patients with open angle glaucoma and ocular hypertension.

4.2 Posology and method of administration

Recommended dosage for adults (including the elderly):

Recommended therapy is: One eye drop in the affected eye(s) once daily. Optimal effect is obtained if Xalatrex is administered in the evening.

The dosage of Xalatrex should not exceed once daily since it has been shown that more frequent administration decreases the intraocular pressure lowering effect.

If one dose is missed, treatment should continue with the next dose as normal.

As with any eye drops, to reduce possible systemic absorption, it is recommended that the lacrimal sac be compressed at the medial canthus (punctal occlusion) for one minute. This should be performed immediately following the instillation of each drop.

Contact lenses should be removed before instillation of the eye drops and may be reinserted after 15 minutes.

If more than one topical ophthalmic drug is being used, the drugs should be administered at least five minutes apart.

Children:

Safety and effectiveness in children has not been established. Therefore, Xalatrex is not recommended for use in children.

4.3 Contraindications

Known hypersensitivity to any component in Xalatrex.

4.4 Special warnings and precautions for use

Latanoprost may gradually change eye colour by increasing the amount of brown pigment in the iris. Before treatment is instituted, patients should be informed of the possibility of a permanent change in eye colour. Unilateral treatment can result in permanent heterochromia.

This 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. In patients with homogeneously blue eyes, no change has been observed and in patients with homogeneously grey, green or brown eyes, the change has only rarely been seen.

The colour change is due to increased melanin content in the stromal melanocytes of the iris and not due to an increase in number of melanocytes. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery in affected eyes, but the entire iris or parts of it may become more brownish. No further increase in brown iris pigment has been observed after discontinuation of treatment.

Neither naevi nor freckles of the iris have been affected by treatment. Accumulation of pigment in the trabecular meshwork or elsewhere in the anterior chamber has not been observed in clinical trials. Based on 5 years clinical experience, increased iris pigmentation has not been shown to have any negative clinical sequelae. Xalatrex can be

continued if iris pigmentation ensues. However, patients should be monitored regularly and if the clinical situation warrants, Xalatrex treatment may be discontinued.
There is limited experience of Latanoprost in chronic angle closure glaucoma, open angle glaucoma of pseudophakic patients and in pigmentary glaucoma. There is no experience of Latanoprost in inflammatory and neovascular glaucoma, inflammatory ocular conditions, or congenital glaucoma. Latanoprost has no or little effect on the pupil, but there is no experience in acute attacks of closed angle glaucoma. Therefore, it is recommended that Xalatrex should be used with caution in these conditions until more experience is obtained.
There are limited study data on the use of Latanoprost during the peri-operative period of cataract surgery. Xalatrex should be used with caution in these patients.
Reports of macular oedema have occurred mainly in aphakic patients, in pseudophakic patients with torn posterior lens capsule or anterior chamber lenses, or in patients with known risk factors for cystoid macular oedema (such as diabetic retinopathy and retinal vein occlusion). Xalatrex should be used with caution in aphakic patients, in pseudophakic patients with torn posterior lens capsule or anterior chamber lenses, or in patients with known risk factors for cystoid macular oedema.
In patients with known predisposing risk factors for iritis/uveitis, Xalatrex can be used with caution.
There is limited experience from patients with asthma, but some cases of exacerbation of asthma and/or dyspnoea were reported in post marketing experience. Asthmatic patients should therefore be treated with caution until there is sufficient experience.
Periorbital skin discolouration has been observed, the majority of reports being in Japanese patients. Experience to date shows that periorbital skin discolouration is not permanent and in some cases has reversed while continuing treatment with Latanoprost.
Latanoprost may gradually change eyelashes and vellus hair in the treated eye and surrounding areas; these changes include increased length, thickness, pigmentation, number of lashes or hairs and misdirected growth of eyelashes. Eyelash changes are reversible upon discontinuation of treatment.
Xalatrex contains benzalkonium chloride, which is commonly used as a preservative in ophthalmic products. Benzalkonium chloride has been reported to cause punctate keratopathy and/or toxic ulcerative keratopathy, and it may cause eye irritation and is known to discolour soft contact lenses. Close monitoring is required with frequent or prolonged use of Xalatrex in dry eye patients, or in conditions where the cornea is compromised. Contact lenses may absorb benzalkonium chloride and these should be removed before applying Xalatrex but may be reinserted after 15 minutes (see Posology and Method of Administration).

4.5 Interaction with other medicinal products
Definitive drug interaction data are not available.
There have been reports of paradoxical elevations in intraocular pressure following the concomitant ophthalmic administration of two prostaglandin analogues. Therefore, the use of two or more prostaglandins, prostaglandin analogues or prostaglandin derivatives is not recommended.

4.6 Pregnancy, fertility and Lactation

Pregnancy
The safety of this medicinal product for use in human pregnancy has not been established. It has potential hazardous pharmacological effects with respect to the course of pregnancy, to the unborn or the neonate. Therefore, Xalatrex should not be used during pregnancy.
Lactation
Latanoprost and its metabolites may pass into breast milk and therefore Xalatrex should not be used in nursing women or breast-feeding should be stopped.

4.7 Effects on ability to drive and use machines
In common with other eye preparations, instillation of eye drops may cause transient blurring of vision. Until this has resolved, patients should not drive or use machines.

4.8 Undesirable effects
The majority of adverse events relate to the ocular system.
Adverse events are categorized by frequency as follows: Very common (≥1/10), common (≥1/100, < 1/10), uncommon (≥1/1000, < 1/100), rare (< 1/1000) and very rare (< 1/10,000). Not known (cannot be estimated from the available data).
Eye Disorders:
Very common: Increased iris pigmentation; mild to moderate conjunctival hyperaemia, eye irritation (burning grittiness, itching, stinging and foreign body sensation); eyelash and vellus hair changes (increased length, thickness, pigmentation and number) (vast majority of reports in Japanese population).
Common: Transient punctate epithelial erosions, mostly without symptoms; blepharitis; eye pain.
Uncommon: Eyelid oedema; dry eye; keratitis; blurred vision; conjunctivitis.
Rare: Iritis/uveitis (the majority of reports in patients with concomitant predisposing factors); macular oedema; symptomatic corneal oedema and erosions; periorbital oedema; misdirected eyelashes sometimes resulting in eye irritation; extra row of cilia at the aperture of the meibomian glands (distichiasis).
Not known: Iris cyst.
Nervous System Disorders:
Not known: Headache, dizziness.
Cardiac Disorders:
Very rare: Aggravation of angina in patients with pre-existing disease.
Not known: Palpitations.
Respiratory, Thoracic and Mediastinal Disorders:
Rare: Asthma, asthma exacerbation and dyspnoea.
Skin and Subcutaneous Tissue Disorders:
Uncommon: Skin rash.
Rare: Localised skin reaction on the eyelids; darkening of the palpebral skin of the eyelids.
Musculoskeletal and Connective Tissue Disorders:
Not known: Myalgia; arthralgia.
General Disorders and Administration Site Conditions:
Very rare: Chest pain.

4.9 Overdose
Apart from ocular irritation and conjunctival hyperaemia, no other ocular side effects are known if Xalatrex is overdosed.
If overdosage with Xalatrex occurs, treatment should be symptomatic.

5. Pharmacological properties
5.1 Pharmacodynamics properties
The active substance latanoprost, a prostaglandin F2 α analogue, is a selective prostanoid FP receptor agonist which reduces the intraocular pressure by increasing the outflow of aqueous humour. Reduction of the intraocular pressure in man starts about three to four hours after administration and maximum effect is reached after eight to twelve hours. Pressure reduction is maintained for at least 24 hours.
Mild to moderate conjunctival or episcleral hyperaemia may occur during topical treatment.
Latanoprost has not induced fluorescein leakage in the posterior segment of pseudophakic human eyes during short-term treatment.

5.2 Pharmacokinetics properties
Latanoprost (mw 432.58) is an isopropyl ester prodrug which per se is inactive, but after hydrolysis to the acid of latanoprost, it becomes biologically active.
The prodrug is well-absorbed through the cornea and all drug that enters the aqueous humour is hydrolysed during the passage through the cornea.
There is practically no metabolism of the acid of latanoprost in the eye. The main metabolism occurs in the liver. The half-life in plasma is 17 minutes in man. The main metabolites, the 1,2-dinor and 1,2,3,4-tetranor metabolites, exert no or only weak biological activity in animal studies and are excreted primarily in the urine.

6. Pharmaceutical particulars:
6.1 List of excipients:
Benzalkonium chloride, sodium chloride, sodium dihydrogen phosphate monohydrate, disodium hydrogen phosphate anhydrous, polysorbate 80, water for injection.

6.2 Incompatibilities:
None known.

6.3 Shelf life:
2 years.

6.4 Special precautions for storage:
Store at a temperature 2°-8°C, and use for 28 days after opening when stored at room temperature.

6.5 Nature and contents of container:

Carton box containing opaque (LDPE) bottle of 2.5 ml with transparent (LDPE) nozzle and (HDPE) tamperproof cap + inner leaflet.

6.6 Special precautions for disposal and other handling:
Any unused medicine or waste material should be disposed of by taking to your local pharmacy.

7. Marketing authorization holder:
EIPICO

8. Date of revision of the text:
August 2024.