Xalatan® 0.005% w/v eye drops solution

Prescribing Information
Please refer to the SmPC before prescribing Xalatan® 0.005% w/v eye drops solution (latanoprost)

Presentation Plastic bottle containing 2.5ml eye drops. Each 1ml contains latanoprost 50 micrograms (0.005%) and benzalkonium chloride. Indication Reduction of elevated intraocular pressure in patients with OAG and ocular hypertension. Reduction of elevated intraocular pressure in paediatric patients with elevated intraocular pressure and paediatric glaucoma. Dosage and Administration Adults including the Elderly: One eye drop into the affected eye(s) once daily in the evening. Contact lenses should be removed before instillation of the eye drops and may be reinserted after 15 minutes (see Precautions). Paediatric population: Xalatan eye drops may be used in paediatric patients at the same posology as in adults. No efficacy and safety data are available for preterm infants (less than 36 weeks gestational age) and data in the age group <1 year is very limited. Contra-indications Known hypersensitivity to any component. Precautions Xalatan may increase brown pigment within the iris leading to a gradual change in eye colour usually within the first 8 months of treatment, rarely during the second or third year, and has not been seen after the fourth year of treatment. The rate of progression of iris pigmentation decreases with time and is stable for five years. The effect of increased pigmentation beyond five years has not been evaluated. In an open 5-year latanoprost safety study, 33% of patients developed iris pigmentation. This has predominantly been seen in patients with mixed coloured irides and may be permanent. Patients should be examined regularly and treatment discontinued if appropriate. Unilateral treatment can result in permanent heterochromia. Exercise caution in patients with asthma, inflammatory ocular conditions and other types of glaucoma, including chronic angle closure, OAG of pseudophakic patients and in pigmentary glaucoma. Xalatan should be used with caution in patients with a history of herpetic keratitis, and should be avoided in cases of active herpes simplex keratitis and in patients with a history of recurrent herpetic keratitis specifically associated with prostaglandin analogues. Also caution is recommended in aphakic patients, pseudophakic patients with torn posterior lens capsule or anterior chamber lenses or patients with known risk factors for cystoid macular oedema. 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. Xalatan contains the preservative benzalkonium chloride which has been reported to cause punctate keratopathy and/or toxic ulcerative keratopathy, may cause eye irritation and is known to discolour soft contact lenses. Close monitoring required with frequent or prolonged use of Xalatan in dry eye patients/conditions where the cornea is compromised. Contact lenses may absorb benzalkonium chloride. These should be removed before applying Xalatan but may be reinserted after 15 minutes (see Dosage and Administration). Paediatric population: In children from 0 to <3 years old that mainly suffers from PCG (Primary Congenital Glaucoma), surgery (e.g. trabeculectomy/goniotomy) remains the first line treatment. Pregnancy Do not use. Lactation Do not use or stop breast feeding.

Driving: 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. Interactions Definitive 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. Any other eye drops should be administered five minutes apart. Paediatric population: Interaction studies have only been performed in adults. Side Effects Ocular side effects - Very common (≥1/10): 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); Common (≥1/100 and <1/10): transient punctate epithelial erosions (mostly without symptoms), blepharitis, eye pain. Please refer to SmPC for other ocular side-effects. Non-ocular side-effects – Uncommon (≥1/1000 and <1/100): Skin rash; Rare (≥1/10,000 and <1/1000): Asthma, asthma exacerbation, dyspnoea, localised skin reaction on the eyelids, darkening of the palpebral skin of the eyelids; Very rare (<1/10,000): Aggravation of angina in patients with pre-existing disease, chest pain. There have been
additional post-marketing spontaneous reports with unknown frequency (cannot be estimated from the available data) of: herpetic keratitis, iris cyst, headache, dizziness, palpitations, myalgia and arthralgia. **Paediatric Population:** In two short term clinical trials (≤ 12 weeks), involving 93 paediatric patients the safety profile was similar to that in adults and no new adverse events were identified. The short term safety profiles in the different paediatric subsets were also similar. Adverse events seen more frequently in the paediatric population as compared to adults are: nasopharyngitis and pyrexia. Long term side effects in children (ie iris pigmentation) have not been established. **Driving** Instillation of eye drops may cause transient blurring of vision. **Overdosage** Symptomatic treatment. **Pharmaceutical Precautions** Store at 2°C - 8°C. Protect from light. Once opened, store at room temperature (≤25°C) and discard after 1 month. **Legal category POM.** **Packaging Quantities and Basic NHS price** 2.5 ml £12.48. **PL number** PL 00057/1057. **PL Holder** Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK. **Date of preparation of PI:** October 2012. Further information is available on request from: Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS, UK.

**Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Pfizer Medical Information on 01304 616161**

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