

2.7 Clinical Summary

Latanoprost/Pharmathen 50 µg/mL preservative free eye drops, solution is indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma and ocular hypertension.

Formulations of latanoprost have been well established in Europe for more than a decade.

Pharmathen S.A. recognizes the fact that latanoprost is an effective and safe substance for its indicated use and has developed a formulation of this medication.

The present marketing authorisation application is related to a medicinal product claiming essential similarity to Xalatan[®] (latanoprost) eye drops solution 50 µg/mL (Pfizer) and authorised pursuant to Article 10(3) hybrid application of Directive 2001/83/EC.

The majority of the clinical data appearing in the current overview are based solely on bibliographical research. The cited articles refer to reviews and/or clinical studies performed in humans.

For a bibliographical research report on all studies carried out on latanoprost please refer to Module 5 of this application.