*Only for the use of Medical Professionals*

# Lotensin® Plus

Timolol Maleate 0.5% + Latanoprost 0.005% eye drops

**Description**

**Lotensin® Plus** is a sterile ophthalmic preparation consists of two components Latanoprost and Timolol maleate. These two components decrease elevated intraocular pressure (lOP) by different mechanisms of action. Latanoprost, a prostaglandin $F_2$ ∞ analogue, is a prostanoid selective prostaglandin $F_2$ (FP) receptor agonist that reduces the lOP by increasing the outflow of aqueous humour.I. Timolol is a β1 and β2 (non-selective) adrenergic receptor blocking agent. Timolol lowers IOP by decreasing aqueous humour formation in the ciliary epithelium.

**Indicatlon**

**Lotensin® Plus** is indicated for the reduction 0f intraocular pressure (l0P) in patients with open-angle glaucoma or ocular hypertension who are insufftciently responsive to β -blockers, prostaglandins or other lOP lowering agents.

**Dose and administration**

The recommended adult (including the elderly) dosage of **Lotensin® plus** is one drop in the affected eye(s) once daily.lf one dose is missed, treatment should continue with the next dose as normal.

Note: Safety and effectiveness in children has not been established. **Lotensin®Plus** is therefore is not recommended for use in children.

**Use in pregnancy & lactation**

No reproduction toxicity studies have been conducted with this combination.This combination should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Latanoprost and its metabolites may pass into breast milk. Timolol maleate has been detected in human milk following ocular administration.Because of the potential serious adverse reactions in nursing infants, this preparation should be used with caution in nursing women.

**Side effects**

This combination is generally well tolerated. The most frequent findings of increased iris pigmentation were in patients wlth green-brown, yellow-brown and blue/grey/brown irides. ln patients with homogenously blue, grey, green or brown eyes, the change was only rarely seen. Darkening, thickening and lengthening of the eye lashes have been reported. The most frequently reported undesirable effects in clinical trials were irritation of the eye, including stinging, burning and ,itching, eye hyperaemia, corneal disorders, coniunctivitisblepharitis, eye pain, headache and skin rash.

**Contraindications**
This combination is contraindicated in patients with Known hypersensitivity to Latanoprost,Timolol and benzalkonium_chloride or any other ingredient in the product. This combination is also contraindicated for the following conditions such as reactive airway disease including bronchial asthma, history of bronchial asthma or severe chronic obstructive pulmonary disease, sinus bradycardia, second or third degree atrioventricular block, overt cardiac failure, or cardiogenic shock.

**Warnings**
This combination may be absorbed systemically. Due to the β-adrenergic component Timolol, aggravation 0f prinzmetal's angina, aggravation of severe eripheral and central circulatory disorders, bradycardia and hypotention may occur. Bronchospasm may occur in asthma patients.Latanoprost may gradually change the eye colour by increasing the amount of brown pigment in the iris.The change in iris colour occurs slowly and may not be noticeable for several months to years.

**Precaution**
This preparation should be used with caution in patients with macular edema,aphakic patients, pseudophakic parients with a torn posterior lens capsule or in patients with known risk factors for macular edema.It should be administered with caution in patients subjected to spontaneous hypoglycaemia or to diabetic patients who are receiving insulin or oral hypoglycaemic agents.Caution should also be exercised to patients wearing contact lenses or drive and use machines.

**Drug interaction**
No specific interaction studies have been performed with this preparation.
Patients who are receiving trearment with this preparation and an oral β -adrenergic blocking agent should be observed for potential additive effects of β-blockade,both systemic and on lntraocular pressure The concomitant use of two topical β-adrenergic blocking agents is not recommended. Although this preparation alone has little or no effect on pupil size, mydriasis has occasionaily been reported when Timolol is given wirh epinephrine.β-blockers may increase the hypoglycemic effect of antidiabetic agents. ln vitro studies have shown that precipitation occurs when eye drops containing thimerosal are mixed with Benzalkonium chloride, the preservative used in this preparatlon.lf such drugs are used they should be administered with an interval of at least 5 minutes between applications. Similarly, several contact lens soakinq solutions contain thimerosal.

**Over-dosage**

There is no human data available on overdosage with this preparation.Symptoms of systemic timolol overdosage are bradycardia,hypotenslon,bronchospasm, and cardiac arrest. lf such symptoms occur,treatment should be symptomatic and supportive. The ocular effects of Latanoprost administered at high doses are not known . lf overdose with this preparation occurs, treatment should be symptomatic.

**Pharmaceutical precautions**
Store in a cool and dry place.Protect from light. Keep away from the reach ofchildren.
Discard container 1 month after opening.

**Presentation**
**Lotensin® Plus** eye drops: Each ml ophthalmic solution contains Timolol 5 mg as Maleate BP & Latanoprost INN 0.05 mg.

**Packaging quantities**
**Lotensin® Plus** eye drops: Each 5ml plastic dropper bottle contains 2.5 ml of **Lotensin® Plus** ophthalmic solution.

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