Nyolol 0,25% / Nyolol 0,50%

Eye Drops
Timolol Maleate

Composition

1 ml contains :	0.25 %	0.50 %
Active substance :		
Timolol maleate	3.4 mg	6.8 mg
Quantity equivalent to timolol base	2.5 mg	5.0 mg

Exipients:Disodium hydrogenphosphate 11.0 mg, Sodium dihydrogen phosphate 8.6 mg, Purified water to 1 ml. Preservative: Benzalkonium chloride 0.1 mg.

Pharmacological data

The action of Nyolol is usually rapid occuring approx. 20 minutes following ocular instillation. The maximum effect occurs in one to two hours and significant lowering of intraocular pressure has been maintained for periods as long as 24 hours with Nyolol 0.25 % or 0.50%.

Nyolol has the action of reducing elevated intraocular pressure, wether or net accompanied by glaucoma.

Pharmacological characteristics of Timolol maleate, the active ingredient of Nyolol eye drops, are:

— non-selective beta-blocking agent
— no intrinsic sympathomimetic activity (I.S.A.)
— non significant local anesthetic effect (membrane stabilizer)

Unlike miotics, Nyolol has practically no effect on pupil size or accomodation. No accomodative spasm nor change in visual acuity are observed.

As with other antiglaucoma drugs, a diminished responsiveness to timolol has been reported in some patients after prolonged therapy.

Pharmacokinetics data

Systemic absorption: plasma levels following ocular installation have not been specified.

Indications

— Ocular hypertension
— Chronic open-angle glaucoma
— Aphakic glaucoma

Contraindications

Absolute:

— Bronchial asthma, bronchospasm, history of bronchial asthma or severe chronic obstuctive pulmonary disease.
— Uncontrolled congestive cardiac insufficiency, cardiogenic shock.
— High atrioventricular block (without apparatus)
— Raynaud phenomena
— Hign bradycardia (pulse rates < 45 to 50 pulses/min.).
— Hypersensitivity to any component.

Relative:

— Combination with amiodarone.

Warnings

Sportsmen should take care that this speciality contains an active product which can induce in a positive way the tests made during antidoping controls.

Precautions

As with other topically applied ophtalmic drugs, this drug may be absorbed systemically and lead to systemic effects of beta-blockers.

Cardiac insufficiency should be adequately controlled before starting therapy with Nyolol. In patients with a history of severe cardiac disease and in elderly patiens, signs of cardiac insufficiency should be watched for and pulse rates should be checked.

Following administration of maleate timolol, severe respiratory reactions and cardiac reactions have been reported, including death due to bronchospasm in patients with asthma, and rarely death in association with cardiac failure.

Patients already receiving a beta-blocker orally and who are given Nyolol should be observed for a potential additive effects of beta-blockers.

Diabetes mellitus

Beta-blockers should be administered with caution in patients subject to spontaneous hypo-glycemia or to diabetic patients (especially those with labile diabetes) who are receiving insulin or oral hypoglycemic agents. Beta-blockers may mask the signs and symptoms of acute hypoglycemia.

Although Nyolol is well tolerated in glaucomatous patients wearing contact lenses as well as in aphakic patients, the wear of contact lenses should be avoided due to the risk of:

— decrease of lacrimal secretion due to beta-blockers
— absorption on the lens of some components of the drug (benzalkonium chloride)
— keratitis while wearing soft contact lenses due to benzalkonium chloride

Use in children

Clinical studies in children have not been conducted.

Nyolol is not recommended in premature baby and newborn.

Use in pregnant woman

Nyolol has not been studied in human pregnancy

Nursing mothers

Beta-blockers are excreted in the milk. The risk of hypoglycemia an bradycardia in nursing infants has not been evaluated. Breast feeding is not recommended during treatment.

Drug interactions and other interactions

Those of beta-blocking agents. Calcium inhibitors, catecholamine depleting drugs, beta-blocking agents may lead to hypotension and/or severe bradycardia and when combined with Nyolol may produce additive effects.

Ophthalmic supervision is required in case of concomitant therapy with eyedrops containing adrenaline (mydriasis may occur).

Adverse reactions

Nyolol ophtalmic solution is generally well-tolerated. In clinical studies of timolol maleate the adverse reactions reported were mainly:

- Ocular: symptoms of ocular irritation, including conjunctivitis, blepharitis, keratitis, corneal hypoesthesis, visual disturbances including refractive changes (due to withdrawal of miotic therapy in some cases), diplopia and ptosis.
- Cadiovascular: bradycardia, arrhythmia, hypotension, syncope, heart block, cerebrovascular accident, cerebral ischemia, congestive heart failure, palpitation, cardiac arrest.
- Respiratory: bronchospasm (predominantly in patients with preexisting bronchospastic disease), respiratory failure, dyspnea.
- Systemic: headache, asthenia, nausea, dizziness, depression, fatigue.
- Integumentary: hypersensitivity reactions, including localized and generalized rash and urticaria, have been reported.

Dosage and administration

The usual starting dose is one drop of 0.25 % Nyolol in the affected eye twice a day.

If the clinical response is not adequate, the dosage may be changed to one drop of 0.5 % solution in the affected eye twice a day.

If necessary the physician may institute a concomitant therapy:

- either a sympathomimetic or parasympathomimetic antiglaucoma ophthalmic solution,
- or systemically administered carbonic anhydrase inhibitors, in order to obtain a better response.

Since in some patients the pressure-lowering response to Nyolol may require a few weeks to stabilize, evaluation should include a determination of intraocular pressure after approximately 4 weeks of treatment with Nyolol.

If the intraocular is maintained at satisfactory levels, the dosage schedule may be changed to on drop once a day.

Substitution to a prior treatment

- When Nyolol should be administered in substitution to another beta-blocking ophthalmic solution, dicontinue this drug at the end of a full-day treatment. On the following day, one drop of Nyolol 0.25 % should be administered in the affected eye twice a day. If a higher dosage of Nyolol is required substitute one drop of Nyolol 0.5 % in the affected eye twice a day.
- When Nyolol should be administered in substitution to a previously used non beta-blocking antiglaucoma ophthalmic solution, continue the agent already being used for one day and add one drop of Nyolol 0.25 % twice a day. On the following day, discontinue the previously used antiglaucoma agent and continue Nyolol 0.25%. If clinical response is not adequate, substitute Nyolol 0.25% with one drop of Nyolol 0.50%.

When Nyolol should be substituted to several concomitantly administered antiglaucoma agents, individualizations is required.

The physician will decide to discontinue one or all the previously used antiglaucoma agents.

When a patient is transferred from miotics to Nyolol, a refractive examination may be required when miotics have no longer effects.

The patient should follow strictly the directions for treatment and intraocular pressure should be controlled particulary at the beginning of the treatment.

Shelf Life

If the pack is unopend, Nyolol eye drops can be used until the expiry date indicated with "EXP" on the pack.

Special storage conditions

To be usend within 30 days after first opening.

Store at room temperature (15°-25°C).

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