TIMO-COMOD 0.5% EYE DROPS
Timolol Maleate 6.84mg/ml (= 5mg/ml)
Antiglaucomatous Agent

PRODUCT DESCRIPTION

Timo-COMOD 0.5% is a clear and colourless solution available in dropper plastic bottle within 10 ml solution.

PHARMACOLOGY

Pharmacodynamics

Antiglaucomatous eye drops for lowering an elevated intracular pressure. Timo-COMOD 0.5% eye drops reduce both elevated and normal intraocular pressures by suppressing the secretion of aqueous humour. The unpigmented epithelium of the ciliary body has many b receptors. Betablockade of these receptors results in an inhibition of aqueous humour secretion. In addition, timolol may reduce the out-flow resistance of aqueous humour.

Pharmacokinetics

The onset of pharmacologic effect is rapid, beginning about 20 minutes after local application to the eye. The maximal reduction of intraocular pressure is reached after one to two hours and a significant decrease in intraocular pressure lasts up to 24 hours.

INDICATIONS AND CLINICAL USE

Timo-COMOD 0.5% is indicated in elevated intraocular pressure, chronic open-angle glaucoma, aphakic glaucoma, congenital glaucoma, if other therapeutic regimens are not sufficient.

DOSAGE AND ADMINISTRATION

Normally, therapy begins with 1 drop twice daily. If the intraocular pressure is adjusted to the required value, the physician may fix the dosage to 1 drop once a day.

Remove the cap covering the nozzle. With a finger retract the lower eye lid until the inner red, moist surface is exposed. Tilt your head back, invert the bottle and gently squeeze out the prescribed number of drops onto the exposed surface of the lower lid avoiding any contact of the bottle with eye or skin.
Timo-COMOD 0.5% is instilled into the conjunctival sac and is suitable for long-term therapy.

MODE OF ADMINISTRATION

For ophthalmic use only

CONTRAINDICATIONS

Timo-COMOD 0.5% is contraindicated in patients with bronchial hyperreactivity, bronchial asthma, severe chronic obstructive pulmonary disease, sinus bradycardia, second and third degree atrio-venticular block, overt cardiac failure, cardiogenic shock, hypersensitivity to

any component of this product, severe allergic rhinitis or nutritional disorders, involving the cornea.

WARNINGS AND PRECAUTIONS

During the usage of Timo-COMOD 0.5% soft contact lenses should not be worn. Hard and soft contact lenses should be removed from the eye before applying the eye drops and being reinserted again 15 minutes after application.

Timo-COMOD 0.5% may cause blurred vision after application even at normal dosages and with proper use. This can subsequently impair reaction time while driving or operating machinery.

DRUG INTERACTIONS

The concurrent application of adrenaline-containing eye drops may cause mydriasis. Timolol's phar~~a~~macological action of reducing intra-ocular pressure is enhanced by adrenaline or pilocarpine-containing eye drops. The concurrent systemic use of beta-blockers may lead to a mutual increase in each drug's pharmacological activity; intraocular reduction by timolol will be enhanced as well as systemic beta-blocking activity on the cardiovascular system. Hypotension and bradycardia may be potentiated by the concurrent use of timolol with oral calcium antagonist, catecholamine-releasers or beta-blockers.

PREGNANCY AND LACTATION

No well-controlled studies in pregnant women exist. The expected benefit has to be balanced very carefully against possible risks by the physician. Please inform your physician if you are nursing or planning a pregnancy. When Timo-COMOD 0.5% eye drops are applied to the mother shortly before delivery, brachycardia, hypoglycemia and respiratory depression in the neonate may occur. Neonates therefore should be observed carefully for several days after delivery. After ocular administration timolol is secreted into breast milk and may accumulate to higher concentrations than in the mother's plasma. Although the amount of active ingredient thus received in breast milk is probably of no risk for the newborn, then child should be carefully observed for symptoms of β-blockade.

ADVERSE REACTIONS

Eyes:

Irritation of the eyes (e.g. burning, stinging, itching, tearing, redness), conjunctivitis, blepharitis, keratitis, impaired vision and choroidal detachment following filtration surgery, diplopia, ptosis and sensation, corneal erosion of dryness of the eye.

Systemic side-effects:

Cardiovascular system:

Bradycardia, arrhythmia, hypotension, syncope, atrioventricular block, cerebrovascular insult, cerebral ischaemia, heart failure, cardiac arrest, palpitations, chest pain, cardiac attack.

Respiratory system:

Bronchospasms (especially in patients with existing bronchospastic disease), respiratory insufficiency, dyspnoea, cough.

Skin:

Hypersensitivities such as local or general exanthemas and urticaria, alopecia, skin rash, exacerbation of psoriasis.

Immune system disorders
Systemic lupus erythematosus, systemic allergic reactions including angioedema, urticaria, localized and generalized rash, pruritus, anaphylactic reaction.

Metabolism and nutrition disorders
Hypoglycaemia.

Psychiatric disorders
Insomnia, depression, nightmares, memory loss, hallucination.

Nervous system disorders
Syncope, cerebrovascular accident, cerebral ischemia, increases in signs and symptoms of myasthenia gravis, giddiness, paraesthesia, and headache.

Vascular disorders
Hypotension, Raynaud's phenomenon, cold hands and feet.

Gastrointestinal disorders
Dysgeusia, nausea, dyspepsia, diarrhoea, dry mouth, abdominal pain, vomiting.

Skin and subcutaneous tissue disorders
Alopecia, psoriasiform rash or exacerbation of psoriasis, skin rash.

Musculoskeletal and connective tissue disorders
Myalgia.

Reproductive system and breast disorders
Sexual dysfunction, decreased libido.

General disorders and administration site conditions
Asthenia/weakness.

OVERDOSAGE

Symptoms:
Local therapy with beta-blockers on the eye may cause severe systemic side-effects in predisposed patients. The active ingredient reaches the vascular circulation system via absorption through the conjunctiva and the mucous membranes of nose and tear duct. The most important side-effects involve the cardiovascular system and the bronchial

tree. Overdosing may lead to severe hypotension, cardiac insufficiency, cardiogenic shock, bradycardia. In addition, respiratory disturbances, bronchial spasm, vomiting, confusion and generalized cramping may occur.

Treatment:
In addition to general measures, vital functions have to be checked and corrected, if necessary, under intensive care conditions.
In addition to general measures, vital functions have to be checked corrected, if necessary, under intensive care conditions. The following antidotes are suitable:
Atropine: 0.5 - 2.0 mg as intravenous bolus injection
Glucagon: Initially 1 - 10 mg intravenously, afterwards 2.0 - 2.5 mg per hour as infustion.
Beta-sympathomimetic drugs, based on body weight and efficacy: Dobutamine, isoprenaline, orciprenaline or epinephrine.
Pacemaker therapy may be indicated in therapy-resistant bradycardia.
Beta-2-sympathomimetric drugs (as aerosol or in case of insufficient activity, as injection) or aminophylline, intravenously, can be given in case of bronchial spasm.
In case of convulsion, slow intravenous application of diazepam is recommended.

STORAGE CONDITIONS
Do not store above 30°C.

AVAILABILITY OF DOSAGE FORMS
10mL

AVAILABLE PACK SIZE
1 x 10ml

MANUFACTURER
Ursapharm Arzneimittel GmbH
66129 Saarbrücken/Germany

DATE OF REVISION
~~5 December 2017~~
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