URSAPHARM				
Kunde:	URSAPHARM Export - Pharmaforte (M) Sdn Bhd	**Lackierung:**	/	
Produkt:	PB TIMOLOL-POS 0,5% 5 ML (IN 10 ML) MY	**Lackaussparung:** ☐	/	
Art.-Nr.:	90.2879	**Pharmacode:**	1692	
Format:	240 x 148 mm (Plano)	**Zusatzspezifikation:**	/	
~~**Blindenschrift (FS):**~~	~~JA / NEIN~~	**Sonstiges:**	/	
Material:	Offset 60 g/qm (UPM Fine, Fa. Nordland)	**Kleinste Schriftgröße:**	9 Punkt	
~~**Kleber (ET):**~~	/	**Farbtoleranz vorhanden:**	~~JA~~ / NEIN	Nr.: FTK_UPH_
Farbe 1: ■	Schwarz (1/1-fbg.)	**Farbtoleranz fertigen: (6-fache Ausfertigung)**	~~JA~~ / NEIN	Nr.: FTK_UPH_
Farbe 2: ☐	/			
Farbe 3: ☐	/			
Farbe 4: ☐	/	**Korrekturabzug Nr.:**	1 (mock-up)	
Farbe 5: ☐	/	**Erstellt:**	11.08.2021	C. Staab
Farbe 6: ☐	/	**Freigabe Kunde:**		
Farbe 7: ☐	/	**Endfreigabe/Gut zum Druck:**		

TIMOLOL-POS® 0.5 % EYE DROPS

Timolol maleate 6.84 mg/ml
(corresponds to 5 mg/ml of timolol)
Antiglaucomatous Agent

PRODUCT DESCRIPTION

Timolol-POS® 0.5 % is a clear and colourless solution available in dropper plastic bottle with 5 ml solution.

Composition:
1 ml solution contains:
Active: 6.84 mg timolol maleate (= 5.0 mg timolol)
Excipients:
Benzalkonium chloride (preservative) 0.05 mg,
monobasic sodium phosphate,
dibasic sodium phosphate, water for injections.

PHARMACOLOGY

Pharmacodynamics

Antiglaucomatous eye drops for lowering an elevated intraocular pressure. Timolol-POS® 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 receptors. Beta-blockade of these receptors results in an inhibition of aqueous humour secretion. In addition, timolol may reduce the outflow resistance of aqueous humour.

Pharmacokinetics

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

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INDICATIONS AND CLINICAL USE

Timolol-POS® 0.5 % is indicated in elevated intraocular pressure, chronic open-angle glaucoma, aphakic glaucoma.

DOSAGE AND ADMINISTRATION

The starting dose is 1 drop of 0.25 % twice daily.
If clinical response is not adequate, the dosage may be changed to 1 drop of 0.5 % twice daily.

Unscrew the cap covering the nozzle. With a finger retract the lower 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. Timolol-POS® 0.5 % are instilled into the conjunctival sac and are suitable for long-term therapy.

MODE OF ADMINISTRATION

For ophthalmic use only

CONTRAINDICATIONS

Timolol-POS® 0.5 % is contraindicated in patients with:
- bronchial hyperreactivity
- bronchial asthma
- severe chronic obstructive pulmonary disease
- sinus bradycardia
- second and third degree atrio-ventricular 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 Timolol-POS® 0.5 %, soft contact lenses should not be worn. Hard contact lenses should be removed from the eye before applying the eye drops and being reinserted again 15 minutes after application. As with other topically applied ophthalmic drugs, this drug may be absorbed systemically. The same adverse reactions found with systemic administration of beta-adrenergic blocking agents may occur with topical administration, such as cardiovascular side-effects (bradycardia, arrhythmia, hypotension, syncope, atrioventricular block, cerebrovascular insult, cerebral ischaemia, heart failure, cardiac arrest palpitations) and respiratory side-effects (bronchospasms [especially in patients with existing bronchospastic disease], respiratory insufficiency, dyspnoea). Safety and effectiveness in children are not established.
Timolol-POS®s 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.

Special advise

The intraocular pressure and cornea should be examined at regular intervals as is indicated for all patients undergoing treatment for glaucoma.

DRUG INTERACTIONS

The concurrent application of adrenaline-containing eye drops may cause mydriasis. Timolol's pharmacological action of reducing intraocular pressure is enchanced 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 pressure 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. When Timolol-POS® 0.5 % eye drops are applied to the mother shortly before delivery, bradycardia, 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 probably of no risk for the newborn, the child should be carefully observed for symptoms of β-blockade.

ADVERSE REACTIONS

Eyes:
Irritation of the eyes, such as conjunctivitis, blepharitis, keratitis, impaired vision, diplopia, ptosis and sensation 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.

Respiratory system:
Bronchospasms (especially in patients with existing bronchospastic disease), respiratory insufficiency, dyspnoea.

Skin:
Hypersensitivities such as local or general exanthems and urticaria, alopecia.

Other side effects:
Headache, weakness, vomiting, giddiness, depression, hallucination.

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 spasms, vomiting, confusion and generalized cramping may occur.
Treatment:
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.
Pace-maker 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

Use before the expiration date (imprinted on the packaging carton). Do not use beyond this date.
Do not use Timolol-POS® 0.5 % longer than 4 weeks after the bottle has been opened.
Keep out of the reach of children!
Do not store above 30°C.

AVAILABILITY OF DOSAGE FORMS

5 mL

AVAILABLE PACK SIZE

1 x 5 ml

MANUFACTURER

URSAPHARM Arzneimittel GmbH
66129 Saarbrücken/Germany

Product registration holder:
Pharmaforte (M) Sdn Bhd
2, Jalan PJU 3/49,
Sunway Damansara
47810 Petaling Jaya

DATE OF REVISION

August 2021