GLAUCOTENSIL® TD PF

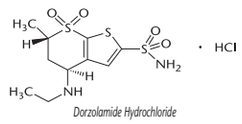
DORZOLAMIDE 2%
TIMOLOL 0.5%

STERILE OPHTHALMIC SOLUTION

Made in Argentina - Rx ONLY

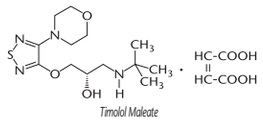
Formula:
Each 100 mL of ophthalmic solution contains:
Dorzolamide (as hydrochloride) 2000 mg
Timolol (as maleate) 500 mg
Sodium citrate anhydrous 294 mg; Hydroxyethyl cellulose 475 mg; Mannitol 2300 mg; Sodium hydroxide 1N q.s. pH 5.4-5.9; Purified water q.s. 100 ml.

Chemical structure:



Dorzolamide Hydrochloride

$C_{10}H_{16}N_2O_4S_3.HCl$
360.9 g/mol



Timolol Maleate

$C_{13}H_{24}N_4O_3S.C_4H_4O_4$
432.5 g/mol

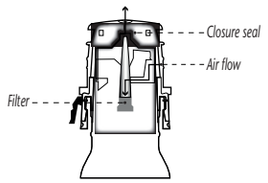
Therapeutical action:
Antiglaucomatous agent.
Combination of a topical carbonic anhydrase inhibitor (Dorzolamide) and a topical beta-adrenergic receptor blocking agent (Timolol).
ATC Code: S01ED51.

Indications:
Treatment of elevated intraocular pressure (IOP) in patients with ocular hypertension, open-angle glaucoma, pseudoexfoliative glaucoma or other secondary open-angle glaucomas who are insufficiently responsive to topical beta-blocker monotherapy.
GLAUCOTENSIL® TD PF differs from standard multidose eye drops in that it is preservative-free (PF). Preservatives can cause serious allergic and inflammatory reactions in the eyes with long-term use in chronic conditions such as ocular hypertension and glaucoma. Preservative-free eye drops, on the other hand, preserve the integrity of the ocular surface. For this reason, GLAUCOTENSIL® TD PF is recommended for patients with sensitive eyes.

Pharmacological characteristics:
Mechanism of action
GLAUCOTENSIL® TD PF is comprised of two active substances: Dorzolamide and Timolol. These two components of the formula decreases elevated intraocular pressure by reducing aqueous humor secretion through different mechanisms of action.
Dorzolamide is a potent inhibitor of human carbonic anhydrase II. Inhibition of carbonic anhydrase in the ciliary processes of the eye decreases aqueous humor secretion by inhibiting the synthesis of bicarbonate ions with subsequent reduction in sodium and fluid transport.
Timolol is a non-selective beta adrenergic receptor blocking agent that does not have significant intrinsic sympathomimetic, direct myocardial depressant, or local anesthetic (membrane-stabilizing) activity.
The combined effect of these two agents results in additional intraocular pressure reduction compared to either component administered alone. Topical ocular administration of GLAUCOTENSIL® TD PF reduces elevated intraocular pressure, regardless of the presence or absence of glaucoma, and without the common side effects of parasympathomimetic antiglaucomatous agents, such as spasm of accommodation or miosis.
Pharmacokinetics
Dorzolamide
When topically applied, Dorzolamide is systemically absorbed. Dorzolamide accumulates in RBCs during chronic dosing as a result of binding to carbonic anhydrase isoenzyme II. N-desethyl metabolite also accumulates in RBCs where it binds primarily to carbonic anhydrase isoenzyme I. Plasma concentrations of Dorzolamide and metabolite N-desethyl are generally below the assay limit of 15nM. Dorzolamide binds moderately to plasma proteins (approximately 33%). Dorzolamide is primarily excreted unchanged in the urine; the metabolite also is excreted in urine.
Timolol
In a study, the systemic exposure to Timolol was determined. Six patients had their plasma drug concentration measured after being administered a 0.5% Timolol topical ophthalmic solution twice a day. The mean peak plasma concentration following morning dosing was 0.46 ng/mL and after the afternoon dosing, it was 0.35 ng/mL.

PRESERVATIVE-FREE - NEW OPHTHALMIC PF VIAL

GLAUCOTENSIL® TD PF is supplied in an OSD (Ophthalmic Squeeze Dispenser, Preservative-Free Multidose System) dropper bottle, specially designed for Preservative-Free (PF) ophthalmic formulations, which consists of a filtration system that prevents contamination of the bottle contents by filtering the air that enters the bottle during use. When the container is squeezed, the pressure forces the closure seal to open, allowing the drop to form. At the same time, the air flow used to balance pressures within the system is forced through a sterile filter (0.2 µm), stopping the entry of particles and microorganisms, thus preventing product contamination and prolonging the shelf-life of the product once the container is opened.



This novel system allows the dosing of preservative-free ophthalmic formulations, avoiding the irritation and cytotoxicity that can be produced by the prolonged use of traditional preservatives, and represents significant benefits for patients with pathologies that require chronic treatment, such as ocular hypertension and glaucoma.
Clinical studies
Corneal endothelial damage was compared in 22 rabbit eyes when they received Dorzolamide/Timolol with and without preservatives. Corneal thickness and opacity
and conjunctival injection were evaluated before and 24 h after treatment. The results showed that corneal endothelial damage was severe in the group that received the product which contained preservatives and minimal in those animals treated with the product which contained no preservatives. For this reason, the investigators conclude that the endothelial toxicity was due to the preservative and not to the active ingredient.
A study of 2298 patients with glaucoma and intolerance to benzalkonium chloride showed that the preservative-free Dorzolamide/Timolol combination applied for 12 weeks reduced intraocular pressure (IOP) and improved local tolerability in 79.3% of patients compared to their previous antiglaucomatous therapy. 80 patients with glaucoma switched from preservative-containing to preservative-free Dorzolamide/Timolol treatment. After 8 weeks, changes were measured on a glaucoma symptom scale. This study demonstrated that preservative-free treatment improves the quality of life of the patients with glaucoma.

Dosage and administration:
Route of administration: TOPICAL OPHTHALMIC USE.
The recommended dosage is one drop of GLAUCOTENSIL® TD PF in the affected eye(s) twice daily, every 12 hours. When replacing other topical ophthalmic antiglaucomatous agent(s) with GLAUCOTENSIL® TD PF, discontinue it(them) after the corresponding administration that day and start GLAUCOTENSIL® TD PF the following day. If other topical ophthalmic products are being used, GLAUCOTENSIL® TD PF and the other products should be administered at least 10 minutes apart.
Method of administration: Tilt the dropper bottle downwards, press it, and administer the dose in the conjunctiva.

Contraindications:
Known hypersensitivity to any of the components of the formula.
Reactive airway disease including bronchial asthma or history of bronchial asthma, or severe chronic obstructive pulmonary disease.
Sinus bradycardia, sick sinus syndrome, sinoatrial block, second- or third-degree atrioventricular block not controlled with pacemakers, overt heart failure, cardiogenic shock.
Severe renal insufficiency (CrCl < 30 mL/ min) or hyperchloremic acidosis.
These contraindications are based on the components and are not exclusive to the combination.

Warnings:
Do not inject. Do not ingest. Product intended for ophthalmic use only.
Do not use the product after the expiration date indicated on the package.
Use the product only if the container is intact.
Keep the dropper bottle carefully closed.
In case of pain in the treated eye(s), irritation or changes in vision, if the condition worsens or persists for more than 72 hours, discontinue use of the product and consult your doctor.
Contamination of topical ophthalmic products
The product is packaged under sterile conditions. To prevent contamination of the dropper bottle tip, avoid touching eyelids, eyelashes and adjacent areas of the eye, or any other surface with the container. Improper handling of the dropper bottle can contaminate it; and then cause serious eye damage, with subsequent decrease in vision. The bottle should be closed immediately after each instillation.
Use of contact lenses
It is recommended to remove the lenses before the instillation of the product and wait 15 minutes before putting your them back.

Precautions:
Cardiovascular / respiratory effects
As with other topically applied ophthalmic products, this drug may be absorbed systemically. The Timolol component is a beta-adrenergic blocker, and therefore the same adverse reactions encountered with systemic administration of beta-adrenergic blockers may occur. Due to the presence of Timolol, heart failure should be appropriately compensated for before initiating treatment with GLAUCOTENSIL® TD PF.
It should be critically evaluated in patients with cardiovascular diseases and in patients on hypotensive therapy with beta-blockers; and therapy with other active ingredients should be considered. Patients with cardiovascular disease with signs of worsening and adverse reactions should be monitored.
Beta-blockers should be administered with caution to patients with first-degree heart block, due to the negative effect on conduction time.
Patients with severe peripheral circulatory disorders should be treated with caution.
Asthmatic patients have died from bronchospasm after administration of ophthalmic beta-blockers.
GLAUCOTENSIL® TD PF should be administered with caution in patients with chronic obstructive pulmonary disease, and only if the benefit outweighs the potential risk.
Renal and hepatic insufficiency
GLAUCOTENSIL® TD PF has not been studied in patients with severe renal insufficiency (CrCl < 30 mL/ min). As Dorzolamide and its metabolite are excreted mainly by the renal route, the use of GLAUCOTENSIL® TD PF is not recommended in these patients. Since GLAUCOTENSIL® TD PF has not been studied in patients with hepatic insufficiency, caution should be exercised in these cases.
Hypersensitivity
As with other topically applied ophthalmic agents, the active ingredients of the product may be absorbed systemically. Dorzolamide is a sulfonamide, and therefore the same adverse reactions as those encountered with systemic administration of sulfonamides may occur, including serious reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis. If signs of serious reactions or hypersensitivity occur, discontinue application of this product.
In clinical studies, ocular adverse effects, mainly conjunctivitis and palpebral reactions, have been reported with prolonged administration of Dorzolamide ophthalmic solution. Some of these reactions had the appearance and development of an allergic-type reaction and resolved when treatment was discontinued. Similar reactions have been reported with the Dorzolamide/Timolol combination. If such reactions are observed, discontinuation of treatment with GLAUCOTENSIL® TD PF should be considered. Patients on beta-adrenergic blocking agents with a history of atopy or severe anaphylactic reaction to allergens may be more susceptible to accidental, diagnostic or repeated therapeutic exposure to such allergens. Such patients may not respond to the usual doses of epinephrine used in the treatment of anaphylactic reactions.
Concomitant treatments
Concomitant administration of Dorzolamide and oral carbonic anhydrase inhibitors is not recommended, due to the possibility of additive effect regarding systemic effects.
Patients already being treated with a systemic beta-adrenergic blocker and administered with GLAUCOTENSIL® TD PF should be monitored for the likelihood of additive effects on both intraocular pressure and known systemic effects of beta-adrenergic blockers. Concurrent use of two topical beta-adrenergic blockers is not recommended.
Angle-closure glaucoma
The treatment of patients with angle-closure glaucoma requires other therapeutic interventions in addition to topical hypotensive agents. GLAUCOTENSIL® TD PF has not been studied in patients with acute angle-closure glaucoma.

Carcinogenesis, Mutagenesis and Fertility
Timolol
In a lifetime study in mice, Timolol caused an increased incidence of malignant lung tumors and breast adenocarcinomas at doses of 500 mg/kg/day orally, but not at doses of 5 or 50 mg/kg/day.
In a 2-year study in rats, Timolol increased the incidence of adrenal pheochromocytomas in male rats at doses of 300 mg/kg/day orally (equivalent to 250 times the maximum recommended human oral dose of 30 mg [1 ophthalmic drop of Timolol contains approximately 1/150 of this dose or approximately 0.2 mg Timolol]). However, no such effects were observed in rats when oral doses equivalent to 20 or 80 times the maximum recommended human oral dose were administered.
In a lifetime study in mice, Timolol increased the incidence of benign lung tumors and benign uterine fibroids in female mice when oral doses of 500 mg/kg/day were administered. However, with doses of 5 and 50 mg/kg/-day this effect was not observed. On the other hand, Timolol increased the overall incidence of neoplasms in female mice treated with oral doses of 500 mg/kg/day (doses well above commonly administered oral doses and much higher than those used in ophthalmology).
Timolol was shown not to be mutagenic in in vivo studies (mouse) by micronucleus test and cytogenetic test with doses up to 800 mg/kg) nor in vivo by neoplastic cell transformation assays with doses up to 0.1 mg/mL.
Reproduction and fertility studies in rats have shown no adverse effects of Timolol on the fertility of male and female animals treated with doses up to 100 times the maximum recommended ophthalmic dose in humans.
Dorzolamide
In a 21-month study in male and female mice, oral administration of Dorzolamide at doses up to 75 mg/kg/day (more than 900 times the recommended ophthalmic dose in humans) did not cause treatment-related tumors. Also, no changes in the bladder epithelium of dogs receiving Dorzolamide orally for one year at doses of 2 mg/kg/day (25 times the recommended human ophthalmic dose) or in monkeys treated topically and ophthalmically for one year with 0.4 mg/kg/day of Dorzolamide (more than 5 times the recommended human ophthalmic dose) were observed. However, in a 2-year study in male and female Sprague-Dawley rats, Dorzolamide administered orally at the highest dose of 20 mg/kg/day (250 times the recommended ophthalmic dose in humans) produced bladder papillomas in male rats. No papillomas were observed in rodents treated with the lowest oral dose, equivalent to 12 times the recommended ophthalmic dose in humans. The higher incidence of bladder papillomas observed in male rats receiving the highest dose correlates with that seen in rats treated with other carbonic anhydrase inhibitors. Rats are particularly prone to develop papillomas in response to foreign bodies, crystalluria-inducing compounds or different sodium salts.
The mutagenic potential of Dorzolamide was studied using the in vivo (mouse) cytogenicity assay, the in vivo chromosome aberration assay, the alkaline dilution assay, the V-79 assay and the Ames test. All of them yielded negative results.
No adverse effects on the reproductive capacity were observed in male and female rats treated with oral doses of Dorzolamide up to 100 times the recommended ophthalmic dose in humans, respectively. No specific controlled human studies have been performed.
Pregnancy
No specific studies have been performed with GLAUCOTENSIL® TD PF in pregnant women. GLAUCOTENSIL® TD PF can be used during pregnancy only when the expected benefit justifies the potential risk to the fetus.
Breastfeeding
It is not known whether Dorzolamide is excreted in human milk. Timolol is detected in breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
Pediatric use
Safety and efficacy of GLAUCOTENSIL® TD PF in children have not been established.
Interactions
No specific interaction studies have been performed with GLAUCOTENSIL® TD PF. Throughout clinical studies, the Dorzolamide/Timolol combination was used concomitantly with the following systemic products without evidence of adverse interactions: ACE inhibitors, calcium channel blockers, diuretics, non-steroidal anti-inflammatory drugs (including acetylsalicylic acid) and hormones (estrogens, insulin, thyroxine). However, there may be additive effects and marked hypotension and/or bradycardia when Timolol in ophthalmic solution is administered together with calcium channel blockers, substances that cause catecholamine depletion, or beta-adrenergic blockers, antiarrhythmics, digitalis glycosides, parasympathomimetics, guanethidine, narcotics and monoamine oxidase inhibitors (MAOIs).
Enhanced systemic beta-blockade has been reported during combined treatment with quinidine and Timolol, probably because quinidine inhibits the metabolism of Timolol via the P-450 CYP2D6 enzyme.
Although GLAUCOTENSIL® TD PF has little or no effect on pupil size, mydriasis has occasionally been reported as a result of concomitant use of ophthalmic beta-blockers with adrenaline (epinephrine). Oral beta-adrenergic blocking agents may exacerbate rebound hypertension that may accompany clonidine withdrawal. Beta-blockers may increase the hypoglycemic effect of antidiabetic drugs.
Dorzolamide is a carbonic anhydrase inhibitor, and although it is administered topically, it is absorbed systemically. Dorzolamide in ophthalmic solution was not associated with acid-base balance disorders. However, such disturbances have been reported with oral carbonic anhydrase inhibitors and, in some cases, have led to drug-drug interactions (e.g. toxicity associated with the administration of high doses of salicylates). Consequently, this possibility and such interactions should be considered in patients treated with GLAUCOTENSIL® TD PF.

Adverse reactions:
GLAUCOTENSIL® TD PF is generally well tolerated. The most frequently reported adverse reactions occurring in up to 30% of patients were taste perversion (bitter, sour, or unusual taste) or ocular burning or stinging. The following adverse reactions were reported in 5-15% of patients: conjunctival hyperemia, blurred vision, superficial keratitis or eye itching. The following adverse reactions were reported in 1-5% of patients: abdominal pain, back pain, blepharitis, bronchitis, cloudy vision, conjunctival discharge, conjunctival edema, conjunctival follicles, conjunctival injection, conjunctivitis, corneal erosion, corneal staining, lens opacity, cough, dizziness, dryness of eyes, dyspepsia, eye debris, eye discharge, eye pain, eye tearing, eyelid edema, eyelid erythema, eyelid exudate, eyelid pain or discomfort, foreign body sensation, glaucomatous cupping, headache, hypertension, influenza, lens nucleus coloration, lens opacity, nausea, nuclear lens opacity, pharyngitis, post-subcapsular cataract, sinusitis, upper respiratory infection, urinary tract infection, visual field defect, vitreous detachment
The following adverse events occurred either with a low incidence (< 1%) throughout clinical studies or were voluntarily reported during use in clinical practice, although neither the population size nor the frequency can be precisely established. They have been selected based on factors such as seriousness, frequency of reporting, possible causal connection with the Dorzolamide/Timolol combination, or a combination of all of these: bradycardia, heart failure, chest pain, stroke, depression, diarrhea, dry mouth, dyspnea, hypotension, iridocyclitis, myocardial infarction, nasal congestion, rash, paresthesia, photophobia, urolithiasis, and vomiting.
Other reactions that have been reported for Dorzolamide include allergic/ hypersensitivity reactions (signs and symptoms of local reactions including eyelid reactions and systemic allergic reactions including angioedema, bronchospasm, puritus, urticaria), skin/ mucous membrane reactions (dermatitis, epistaxis, throat irritation), special sensations (ocular crusting, ocular allergic reaction, transient myopia), asthenia, fatigue.
For Timolol, the following adverse reactions were reported: asthenia, fatigue, arrhythmia, syncope, cerebral ischemia, worsening of angina pectoris, palpitation, cardiac arrest, pulmonary edema, edema, claudication, Raynaud's phenomenon, cold hands and feet, anorexia, lupus erythematosus, increase in symptoms of myasthenia gravis, somnolence, insomnia, nightmares, behavioral changes, psychic disturbances (confusion, hallucinations, anxiety, disorientation, nervousness, memory loss), alopecia, psoriasiform rash or exacerbation of psoriasis, systemic allergic reactions (anaphylaxis, angioedema, urticaria), bronchospasm, masked symptoms of hyperglycemia in diabetic patients, ptosis, decreased corneal sensitivity, cystoid macular edema, visual disturbances, tinnitus, pseudopemphigoid, retroperitoneal fibrosis, decreased libido, impotence, and Peyronie's disease.

Overdosage:
No data are available regarding accidental or intentional overdosage with GLAUCOTENSIL® TD PF in humans. Accidental overdosage with Timolol ophthalmic solution causes systemic effects similar to those seen with systemic beta-adrenergic receptor blockers such as dizziness, headache, respiratory distress, bradycardia, bronchospasm and cardiac arrest. The most common signs and symptoms that can be expected from Dorzolamide overdosage would be electrolyte balance disturbances, acidosis and central nervous system effects. Treatment should be symptomatic and supportive. Serum electrolyte levels (especially potassium) and blood pH values should be monitored. Studies have shown that Timolol is not easily dialyzable.
If an overdosage occurs, go to the nearest hospital or toxicology centers.

How supplied:
Package containing 1 dropper bottle with 5 ml of sterile ophthalmic solution.

PATIENT INFORMATION

"Read this information carefully before using this medicine. Keep this leaflet as you may need to read it again. If you have any questions, ask your doctor or pharmacist. This medicine has been prescribed only for you; do not give (or recommend) it to others, even if they have the same symptoms, as it may harm them. This information is not a substitute for talking to your doctor about your condition or treatment. This medicine must be indicated and prescribed by your doctor. If you think that any of the side effects you are experiencing are serious or if any undesirable effects not mentioned in this leaflet occur, please tell your doctor or pharmacist."

WHAT IS GLAUCOTENSIL® TD PF AND WHAT IS IT USED FOR?
GLAUCOTENSIL® TD PF is an antiglaucomatous agent composed of two drugs (Dorzolamide and Timolol). It differs from standard multidose eye drops in that it is preservative free (PF). Preservatives can cause serious allergic and inflammatory reactions in the eyes with long-term use in chronic conditions, such as ocular hypertension and glaucoma. Preservative-free eye drops, on the other hand, preserve the integrity of the surface of the eye. For this reason, GLAUCOTENSIL® TD PF is recommended for patients with sensitive eyes.

CONSULT YOUR DOCTOR BEFORE USING GLAUCOTENSIL® TD PF:
- If you are allergic to any of the components of the formula.
- If you have respiratory, heart, renal or hepatic disorders, or metabolic acidosis.
- If you are pregnant or nursing.
- If a child will receive the treatment.
- Inform your doctor if you are receiving any other medication.

WHO SHOULD NOT USE GLAUCOTENSIL® TD PF?
Patients with heart or respiratory problems, severe renal diseases, hyperchloremic acidosis or who are allergic to any of the components of the formula.

APPROPRIATE USE OF THE MEDICINE:
For topical ophthalmic use only.

HOW MUCH, WHEN AND HOW IS GLAUCOTENSIL® TD PF USED?
GLAUCOTENSIL® TD PF is indicated for the treatment of elevated intraocular pressure (IOP) in patients with ocular hypertension, open-angle glaucoma, pseudoexfoliative glaucoma or other secondary open-angle glaucomas when single drug therapy is insufficient.
The recommended dosage is one drop of GLAUCOTENSIL® TD PF in the affected eye(s), twice daily, every 12 hours. When replacing other topical ophthalmic antiglaucomatous agent(s) with GLAUCOTENSIL® TD PF, discontinue it/them after the corresponding administration that day and start GLAUCOTENSIL® TD PF the following day.
If other topical ophthalmic products are used, GLAUCOTENSIL® TD PF and the other products should be instilled at least 10 minutes apart.
Method of administration: Tilt the dropper bottle downwards, press it, and administer the dose in the conjunctiva.
Do not inject. Do not ingest. Product intended for ophthalmic use only.
Do not use the product after the expiration date indicated on the package.
Use the product only if the container is intact.
Keep the dropper bottle carefully closed.
In case of pain in the treated eye(s), irritation or changes in vision, if the condition worsens or persists for more than 72 hours, discontinue use of the product and consult your doctor.

CONTAMINATION PREVENTION
The product is packaged under sterile conditions. The dropper bottle tip should be handled correctly, avoiding contact with the eye, eyelashes and adjacent areas or any other surface, in order to avoid contamination with bacteria that commonly cause eye infections. Contaminated product use can cause serious eye damage, with subsequent decrease in vision.
The dropper bottle should be closed immediately after use.

ADDITIONAL INFORMATION
It is recommended to remove the lenses before instillation of the product and wait 15 minutes before putting them back.

POSSIBLE ADVERSE EFFECTS
GLAUCOTENSIL® TD PF is generally well tolerated. The most frequent adverse reactions reported by up to 30% of patients were taste alteration (bitter, sour or unusual taste) and burning or stinging sensation in the eyes. Red eye, blurred vision, corneal inflammation and itching of the eyes were reported in 5-15% of cases. The following adverse effects were reported in 1 to 5% of patients: abdominal pain, back pain, ocular, respiratory, digestive and urinary disorders, hypertension, headache, vertigo and nausea.
The following adverse events occurred at low incidence (< 1%): decreased heart rate, heart failure, chest pain, stroke, depression, diarrhea, dry mouth, shortness of breath, hypotension, inflammation of the ciliary body and ocular iris, myocardial infarction, nasal congestion, rash, abnormal sensory sensation, abnormal light intolerance, renal tract obstruction, and vomiting.
Other reactions that have been reported for Dorzolamide include allergic/ hypersensitivity reactions (eyelid, skin and respiratory tract), skin/ mucous membrane reactions (skin inflammation, nasal bleeding, throat irritation), special sensory effects (ocular crusting, ocular allergic reaction, transient blurred vision of distant objects), weakness, fatigue.
For Timolol, adverse reactions such as tiredness, decay, heart rhythm disorder, loss of consciousness, arrest of breathing and heartbeat, interruption of blood flow to the brain, worsening of angina pectoris, palpitations, accumulation of fluid in the lungs, excess fluid in any organ or tissue, blood circulation disorders, eating disorders, autoimmune diseases, sleep or lack of sleep, nightmares, behavioral changes, psychic disturbances (confusion, hallucinations, anxiety, disorientation, nervousness, memory loss), hair loss, allergic reactions (presented in skin and respiratory tract), masked symptoms of hypoglycemia in diabetic patients, ocular and visual disturbances, tinnitus, erosions and disturbances in mucous membranes, disturbances in the gastrointestinal and genital systems were observed.

REMINDER
This medicine has been prescribed only for your current medical problem. Do not recommend it to others.

Storage conditions:
Store below 30°C.

Discard the product after three months of being opened.

Keep drugs out of reach of children.

Delicate use product. To be administered under prescription and medical surveillance.

Manufactured by: **LABORATORIOS POEN S.A.U.**
Bermúdez 1004 - C1407BDR Buenos Aires, Argentina

Technical Director:
Victor D. Colombari, Pharmacist

4274029840
699
C.V. 1 - 39

669

669

Nombre y Firma/ Nome and Signature — Día/ Day — Mes/ Month — Año/ Year

DIRECCIÓN TÉCNICA

ASUNTOS REGULATORIOS

DESARROLLO

CCA N°: _____

surcan	**SURCAN S.R.L.** Alvarez Thomas 198 3°A Buenos Aires - C1427CCO Tel. 11 44370014 disenografico@surcan.com.ar www.surcan.com.ar	Laboratorio/Laboratory: **LABORATORIOS POEN** Producto/Product: **GLAUCOTENSIL TD PF** Contenido/Content: **SOLUCION** País/Country: **EXPORTACIÓN INGLÉS** Elemento/Item: **PROSPECTO (DORSO Y FRENTE)**	**Tamaño/Size:** **ancho/wide:** 150 mm **alto/high:** 240 mm N° Material: **4274029840** Pharmacode N°: **699** Código visual/Visual code: **1 - 39**	Fecha/Date: **23/JUN/25** Versión N°: **1** **Guía de colores/Colours Guide** Pantone Black C Colores/Colours: **1**