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Worldwide Patient Product Information (WPPI)

Information for the Patient about

TRUSOPT®

PLEASE READ THIS LEAFLET CAREFULLY BEFORE YOU START TO TAKE YOUR MEDICINE, EVEN IF YOU HAVE JUST REFILLED YOUR PRESCRIPTION. SOME OF THE INFORMATION IN THE PREVIOUS LEAFLET MAY HAVE CHANGED.

REMEMBER THAT YOUR DOCTOR HAS PRESCRIBED THIS MEDICINE ONLY FOR YOU. NEVER GIVE IT TO ANYONE ELSE.

What is TRUSOPT?

TRUSOPT® (dorzolamide hydrochloride ophthalmic solution) is a sterile eye drop. It contains 2% dorzolamide hydrochloride, a sulfonamide-related compound, as the active ingredient.

In addition, TRUSOPT contains the following inactive ingredients: Hydroxyethyl cellulose, mannitol, sodium citrate [dihydrate], sodium hydroxide and water for injection. Benzalkonium chloride is added as a preservative.

TRUSOPT is available in bottles containing 5 mL of solution.

TRUSOPT is an ophthalmic carbonic anhydrase inhibitor which lowers pressure in the eye.

Product License Holder:
Santen Pharmaceutical Asia Pte. Ltd.
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Why has my doctor prescribed TRUSOPT?

TRUSOPT is prescribed to lower raised pressure in the eye and to treat glaucoma.

Information I should know before or while using TRUSOPT.

Who should not use TRUSOPT?

Do not use TRUSOPT if you are allergic to any of its components.

What should I tell my doctor (or pharmacist) before or while using TRUSOPT?

Tell your doctor [or pharmacist] about any medical problems you have now or have had in the past and about any allergies to any medications.

If you develop any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelids, contact your doctor immediately.

If you suspect that TRUSOPT is causing an allergic reaction (for example, skin rash or itching) stop its use and contact your doctor as soon as possible.

If you wear contact lenses, you should consult your doctor before using TRUSOPT.

Use in children.

Trusopt is not recommended for use in children.

Use in the Elderly.

In studies with TRUSOPT, the effects of TRUSOPT were similar in both elderly and younger patients.

Use in Pregnancy and Breast Feeding.

Pregnancy
Tell your doctor if you are pregnant or intend to become pregnant. Your doctor will decide if you should use TRUSOPT.

Breast Feeding
Tell your doctor if you are breast feeding or intend to breast feed. Your doctor will decide if you should use TRUSOPT.

Use in patients with significant kidney or liver impairment.

Tell your doctor if you now have or have had in the past kidney or liver problems.

Can I use TRUSOPT with other medicines?

Tell your doctor about all drugs (including eye drops) that you are using or plan to use, including those obtained without a prescription, particularly large doses of aspirin or sulfa drugs.

Can I drive or operate machinery while using TRUSOPT?

There are possible side effects of TRUSOPT that may affect your ability to drive or operate machinery. (See ***What undesirable effects may TRUSOPT have?***)

What should I know about the inactive ingredients in TRUSOPT?

TRUSOPT contains the preservative benzalkonium chloride. This preservative may be deposited in soft contact lenses. If you wear contact lenses you should consult your doctor before using TRUSOPT.

How should I take TRUSOPT?

The appropriate dosage and duration of treatment will be established by your doctor.

When TRUSOPT is used alone, the dose is one drop in the affected eye(s) in the morning, in the afternoon and in the evening.

If your doctor has recommended you use TRUSOPT with a beta-blocker eye drop to lower eye pressure, then the dose is one drop of TRUSOPT in the affected eye(s) in the morning and in the evening.

If you are using TRUSOPT with another eye drop, the drops should be instilled at least 10 minutes apart.

Do not change the dosage of the drug without consulting your doctor. If you must stop treatment, contact your doctor immediately.

Do not allow the tip of the container to touch the eye or areas around the eye.

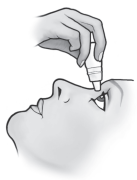
To avoid possible contamination, keep the tip of the container away from contact with any surface.

Instructions for Use:

TRUSOPT Ophthalmic Solution

Do not use the bottle if the plastic safety strip around the neck is missing or broken. When opening the bottle for the first time, tear off the plastic safety strip.

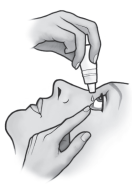
Every time you use TRUSOPT:
1. Wash your hands
2. Open the bottle. Take special care that the tip of the dropper bottle does not touch your eye, the skin around your eye or your fingers.
3. Tilt your head backwards and hold the bottle upside down over the eye.



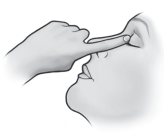
4. Pull the lower eyelid downwards and look up. Gently squeeze the bottle and let one drop fall into the space between the lower eyelid and the eye.

DO NOT TOUCH YOUR EYE OR EYELID WITH THE DROPPER TIP.

Ophthalmic medications, if handled improperly, can become contaminated by common bacteria known to cause eye infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated ophthalmic medications. If you think your medication may be contaminated, or if you develop an eye infection, contact your doctor immediately concerning continued use of this bottle.



5. Press a finger into the corner of your eye, by the nose, or close your eyelids for 2 minutes. This helps to stop the medicine from getting into the rest of the body.



6. Repeat steps 3 to 5 with the other eye if instructed to do so by your doctor.
7. Put the cap back on and close the bottle tightly.

What should I do in case of an overdose?

If the contents of the container are swallowed, you should contact your doctor immediately.

What should I do if I miss a dose?

It is important to take TRUSOPT as prescribed by your doctor. If you miss a dose, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule.

What undesirable effects may TRUSOPT have?

Any medicine may have unintended or undesirable effects, so-called side effects.

Patients may experience eye symptoms such as burning and stinging, blurred vision, itching, tearing, redness of the eye(s), eye pain, or swelling or crusting of the eyelids. You may sense a bitter taste or throat irritation after putting in your eye drops.

Other side effects include headache, nose bleed, dry mouth, nausea, tiredness, dizziness, tingling sensation, kidney stones, and rarely allergic-type reactions including rash, hives and itching and shortness of breath.

Side effects, other than those listed above, may also occur rarely, and some of these may be serious, such as severe skin reactions. Ask your doctor or pharmacist for more information about side effects. Both have a more complete list of side effects.

Please tell your doctor [or pharmacist] promptly about these or any other unusual symptom.

How can I learn more about TRUSOPT, increased eye pressure or glaucoma?

You may obtain further information from your doctor or pharmacist, who have more detailed information about TRUSOPT and your eye condition.

How long will my medicine last?

Do not use this medicine after the month and year shown following EX (or EXP) on the container. Three letters or two numbers indicate the month; the last four numbers indicate the year.

How should I store TRUSOPT?

TRUSOPT Ophthalmic Solution: Store at or below 30°C. Protect from light.
Discard one month after first opening.

Keep all medicines safely away from children.

When was this package leaflet last revised?

This package leaflet was last revised in Apr-2021.

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PACKAGE INSERT
Sterile Ophthalmic Solution

TRUSOPT®

(dorzolamide hydrochloride ophthalmic solution)

Santen

THERAPEUTIC CLASS

TRUSOPT® (dorzolamide hydrochloride ophthalmic solution) is a novel carbonic anhydrase inhibitor formulated for topical ophthalmic use. Unlike oral carbonic anhydrase inhibitors, TRUSOPT, which is administered topically, exerts its effects directly in the eye.

INDICATIONS

TRUSOPT Ophthalmic Solution is indicated in the treatment of elevated intraocular pressure in patients with:

- ocular hypertension
- open-angle glaucoma
- pseudoexfoliative glaucoma and other secondary open-angle glaucomas

DOSAGE AND ADMINISTRATION

When used as monotherapy, the dose is one drop of TRUSOPT Ophthalmic Solution in the affected eye(s) three times daily.

When used as adjunctive therapy with an ophthalmic beta-blocker, the dose is one drop of TRUSOPT in the affected eye(s) two times daily.

When substituting TRUSOPT for another ophthalmic antiglaucoma agent, discontinue the other agent after proper dosing on one day, and start TRUSOPT on the next day.

If more than one topical ophthalmic drug is being used, the drugs should be administered at least ten minutes apart.

CONTRAINDICATIONS

TRUSOPT is contraindicated in patients who are hypersensitive to any component of this product.

PRECAUTIONS

TRUSOPT has not been studied in patients with severe renal impairment (CrCl <30mL/min). Because TRUSOPT and its metabolite are excreted predominantly by the kidney, TRUSOPT is not recommended in such patients.

The management of patients with acute angle-closure glaucoma requires therapeutic interventions in addition to ocular hypotensive agents. TRUSOPT has not been studied in patients with acute angle-closure glaucoma.

TRUSOPT has not been studied in patients with hepatic impairment and should therefore be used with caution in such patients.

TRUSOPT is a sulfonamide and although administered topically, is absorbed systemically. Therefore the same types of adverse reactions that are attributable to sulfonamides may occur with topical administration, including severe reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis. If signs of serious reactions or hypersensitivity occur, discontinue the use of this preparation.

In clinical studies, local ocular adverse effects, primarily conjunctivitis and lid reactions, were reported with chronic administration of TRUSOPT. Some of these reactions had the clinical appearance and course of an allergic-type reaction that resolved upon discontinuation of drug therapy. If such reactions are observed, discontinuation of treatment with TRUSOPT should be considered.

There is a potential for an additive effect on the known systemic effects of carbonic anhydrase inhibition in patients receiving an oral carbonic anhydrase inhibitor and TRUSOPT. The concomitant administration of TRUSOPT and oral carbonic anhydrase inhibitors has not been studied and is not recommended.

Choroidal detachment has been reported with administration of aqueous suppressant therapy (e.g., dorzolamide) after filtration procedures.

TRUSOPT Ophthalmic Solution contains the preservative benzalkonium chloride, which may be absorbed by soft contact lenses. Therefore, TRUSOPT should not be administered while wearing soft contact lenses. The contact lenses should be removed before application of the drops and not be reinserted earlier than 15 minutes after use.

There is an increased potential for developing corneal edema in patients with low endothelial cell counts. Precautions should be used when prescribing TRUSOPT to this group of patients.

PREGNANCY

There are no adequate and well controlled studies in pregnant women. TRUSOPT should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

NURSING MOTHERS

It is not known whether this drug is excreted in human milk. 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 effectiveness in children have not been established.

DRUG INTERACTIONS

Specific drug interaction studies have not been performed with TRUSOPT Ophthalmic Solution. In clinical studies, TRUSOPT was used concomitantly with the following medications without evidence of adverse interactions: timolol ophthalmic solution, betaxolol ophthalmic solution and systemic medications, including ACE-inhibitors, calcium channel blockers, diuretics, non-steroidal anti-inflammatory drugs including aspirin, and hormones (e.g. estrogen, insulin, thyroxine).

TRUSOPT is a carbonic anhydrase inhibitor and although administered topically, is absorbed systemically. In clinical studies, TRUSOPT was not associated with acid-base disturbances. However, these disturbances have been reported with oral carbonic anhydrase inhibitors and have in some instances, resulted in drug interactions (e.g. toxicity associated with high-dose salicylate therapy). Therefore, the potential for such drug interactions should be considered in patients receiving TRUSOPT.

SIDE EFFECTS

In the previous long-term clinical studies of 1108 patients treated with TRUSOPT Ophthalmic Solution alone or as adjunctive therapy with ophthalmic beta-blockers, the most frequently reported drug-related adverse effects and local symptoms were: bitter taste, burning and stinging, blurred vision, eye itching, tearing, headache, conjunctivitis, eyelid inflammation, nausea, eyelid irritation and asthenia/fatigue. The most frequent cause of discontinuation (approximately 3%) from treatment with TRUSOPT was drug-related ocular adverse effects, primarily conjunctivitis and lid reactions. Iridocyclitis and rash were each reported rarely. There was one report of urolithiasis.

The following adverse reactions have been reported in post-marketing experience:

Cardiac disorders: Palpitations

Hypersensitivity: signs and symptoms of local reactions including palpebral reactions and systemic allergic reactions including angioedema, bronchospasm, urticaria and pruritus

Nervous System: dizziness, paresthesia

Ocular: pain, redness, superficial punctate keratitis, transient myopia (which resolved upon discontinuation of therapy), eyelid crusting, choroidal detachment following filtration surgery

Skin/Mucous Membranes: contact dermatitis, epistaxis, throat irritation, dry mouth, Stevens-Johnson syndrome, toxic epidermal necrolysis

Urogenital: urolithiasis.

Laboratory Findings

TRUSOPT was not associated with clinically meaningful electrolyte disturbances.

OVERDOSAGE

Treatment should be symptomatic and supportive. Electrolyte imbalance, development of an acidotic state, and possible central nervous system effects may occur. Serum electrolyte levels (particularly potassium) and blood pH levels should be monitored.

AVAILABILITY

TRUSOPT is available as 2% in 5ml bottle.

The bottle is made up of a white translucent low-density polyethylene bottle, a transparent dropper tip and a white cap.

TRUSOPT Ophthalmic Solution is a clear, colorless to nearly colorless, slightly viscous solution.

Storage

Store at or below 30°C. Protect from light.
Discard one month after first opening.

MANUFACTURED BY
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03