

TRUSOPT[®]

Dorzolamide hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TRUSOPT. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using TRUSOPT against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What TRUSOPT is used for

TRUSOPT is used to lower raised pressure in the eye and to treat glaucoma. Glaucoma is a condition in which the pressure of fluid in the eye may be high. However, some people with glaucoma may have normal eye pressure. Also, some people with raised eye pressure may not have glaucoma.

Glaucoma is caused by a build-up of the fluid which flows through the eye. This build-up occurs because the fluid drains out of your eye more slowly than it is being pumped in. Since new fluid continues to enter the eye, joining the fluid already there, the pressure continues to rise. This raised pressure may damage the back of the eye resulting in gradual loss of sight. Damage can progress so slowly that the person is not aware of this gradual loss of sight.

Sometimes even normal eye pressure is associated with damage to the back of the eye.

There are usually no symptoms of glaucoma. The only way of knowing that you have glaucoma is to have your eye pressure, optic nerve and visual field checked by an eye specialist or optometrist. If glaucoma is not treated it can lead to serious problems. You may have no symptoms but eventually glaucoma can lead to total blindness. In fact, untreated glaucoma is one of the most common causes of blindness.

Although TRUSOPT helps control your glaucoma it does not cure it.

TRUSOPT is used, either alone or in combination with other eye drops or medicines, to lower raised pressure within your eye(s).

TRUSOPT lowers pressure in the eye by reducing the production of fluid.

TRUSOPT belongs to a family of medicines called carbonic anhydrase inhibitors.

TRUSOPT is not addictive.

Before you use TRUSOPT

When you must not use it

Do not use TRUSOPT if:

- **you have an allergy to TRUSOPT or any of the ingredients listed at the end of this leaflet**
- **you are breast-feeding or intend to breast-feed**

It is not known whether TRUSOPT passes into breast milk.

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses.

The preservative in TRUSOPT (benzalkonium chloride) may be deposited in soft contact lenses. You can put your soft contact lenses back into your eyes at least 15 minutes after you have used TRUSOPT.

Do not use TRUSOPT if:

- **the seal around the cap is broken**
- **the bottle shows signs of tampering**
- **the expiry date on the pack has passed.**

If you use this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start using TRUSOPT, talk to your doctor.

Do not give TRUSOPT to a child.

The safety and effectiveness of TRUSOPT in children have not been established.

Before you start to use it

Tell your doctor if:

1. **you are pregnant or intend to become pregnant**

Your doctor will discuss the risks and benefits of using TRUSOPT during pregnancy and a decision can be made if you should or should not use it.

2. **you have now or have had in the past any medical conditions, especially the following:**

- kidney disease
- liver disease

3. **you have an allergy to sulfonamide medicines**

The active ingredient of TRUSOPT, dorzolamide hydrochloride, is a sulfonamide-related compound. Therefore, if you are allergic to sulfonamide medicines you may be allergic to TRUSOPT. Check with your doctor or pharmacist if you are not sure whether you are allergic to sulfonamides.

4. **you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**

If you have not told your doctor about any of the above, tell them before you use TRUSOPT.

Taking other medicines

Tell your doctor if you are using any other medicines or eye drops, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and TRUSOPT may interfere with each other. These include:

- tablets used to treat glaucoma
- large amounts of aspirin or salicylates

These medicines may be affected by TRUSOPT, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using TRUSOPT.

How to use TRUSOPT

How much to use

Your doctor will tell you how many drops you need to use each day.

Use TRUSOPT only when prescribed by your doctor.

When TRUSOPT is used alone, the usual dose for adults is one drop three times a day, in either one or both eyes.

If your doctor has recommended that you use TRUSOPT with a beta-blocker eye drop, then the usual dose for adults is one drop of TRUSOPT twice a day, in either one or both eyes.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

After using TRUSOPT, wait at least 10 minutes before putting any other eye drops in your eye(s).

When to use it

If you are using TRUSOPT three times a day, use the drops first thing in the morning, in the early afternoon and at bedtime (i.e. approximately 8 hours apart). If you are using TRUSOPT twice a day, use the drops in the morning and in the evening (i.e. approximately 12 hours apart).

Use TRUSOPT every day, at about the same time each day, unless your doctor tells you otherwise.

Using your eye drops at the same time each day will have the best effect on your eye pressure. It will also help you remember when to use the eye drops.

How to use it

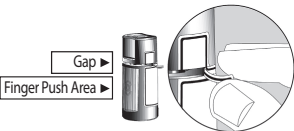
You may find it easier to put drops in your eye while you are sitting or lying down.

Before opening the bottle for the first time, make sure the Safety Strip on the front of the bottle is not broken. If it is, do not use the bottle and return it to your pharmacist.

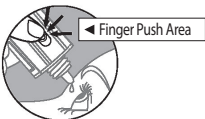
You will notice a small space between the cap and the bottle - this is normal.

If you are wearing soft contact lenses, remove them before putting the drops in your eye.

1. Wash your hands well with soap and water.
2. To open the bottle for the first time, hold the bottle upright and tear off the Safety Strip to break the seal.



3. Place the cap upside down (arrows face down) on a flat surface. Do not touch the inside of the cap. This will help keep the inside of the cap clean and keep germs out of the eye drops.
4. Hold the bottle upside down in one hand, with your thumb or index finger over the "finger push" area.



5. Using your other hand, gently pull down your lower eyelid to form a pouch.
6. Tilt your head back and look up.



7. Put the tip of the bottle close to your lower eyelid. Do not let it touch your eye.
 8. Release one drop into the pouch formed between your eye and eyelid by gently squeezing the bottle.
 9. Close your eye and keep it closed. Do not blink or rub your eye.
 10. While your eye is still closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body. Ask your doctor for more specific instructions on this technique.
 11. Replace the cap, sealing it tightly. Do not overtighten the cap.
 12. Wash your hands again with soap and water to remove any residue.
- Wait at least 15 minutes before replacing your contact lenses.**
Be careful not to touch the dropper tip against your eye, eyelid or anything else to avoid contaminating the eye drops.
Contaminated eye drops may give you an eye infection.
You may feel a slight burning sensation in the eye shortly after using the eye drops.
If this persists, or is very uncomfortable, contact your doctor or pharmacist.

How long to use it

TRUSOPT helps control your condition but does not cure it. Therefore TRUSOPT must be used every day. Continue using TRUSOPT for as long as your doctor prescribes.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use the drops as soon as you remember, and then go back to using them as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not use double the amount to make up for the dose that you missed.

If you have trouble remembering to use your eye drops, ask your pharmacist for some hints.

If you use too much (overdose)

If you think that you or anyone else may have swallowed any or all of the contents of a bottle of TRUSOPT, or used too many drops, immediately contact your doctor or go to accident and emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are using TRUSOPT

Things you must do

Have your eye pressure checked when your eye specialist says, to make sure TRUSOPT is working.

If you develop an eye infection, receive an eye injury, or have eye surgery tell your doctor.

Your doctor may tell you to use a new container of TRUSOPT because of possible contamination of the old one, or may advise you to stop your treatment with TRUSOPT.

If you become pregnant while using TRUSOPT tell your doctor.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are using TRUSOPT.

Things you must not do

Do not give TRUSOPT to anyone else, even if they have the same condition as you.

Do not stop using TRUSOPT without first talking to your doctor.

If you stop using your eye drops, your eye pressures may rise again and damage to your eye may occur.

Things to be careful of

Be careful driving or operating machinery until you know how TRUSOPT affects you.

TRUSOPT generally does not cause any problems with your ability to drive a car or operate machinery. However, it may cause certain side effects in some people, including blurred vision and dizziness. Make sure you know how you react to TRUSOPT before you drive a car or operate machinery.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using TRUSOPT.

TRUSOPT helps most people with high eye pressure and glaucoma, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- eye problems such as burning, stinging, itching, conjunctivitis, watering of the eye(s), redness of the eye(s), swelling or crusting of the eyelids(s), eye pain, blurred vision
- feeling sick
- bitter taste, dry mouth
- nose bleeds
- throat irritation
- headache, dizziness
- tiredness, weakness
- kidney stones
- numbness or tingling in fingers or toes

These are usually mild side effects of TRUSOPT.

If any of the following happen, stop using TRUSOPT and tell your doctor immediately or go to accident and emergency at your nearest hospital:

- wheezing, difficulty in breathing, shortness of breath
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing or swallowing
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash
- skin rash, itchiness

These may be serious side effects.

You may have an allergic reaction to TRUSOPT. You may need urgent medical attention. Serious side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using TRUSOPT

Storage

Keep your eye drops in a cool dry place. Do not store above 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Do not carry the eye drops in pockets of your clothes.

Heat and dampness can destroy some medicines.

Keep the eye drops away from light.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not leave the cap off the bottle for any length of time to avoid contaminating the eye drops.

Disposal

Write the date on the bottle when you open the eye drops and throw out any remaining solution after four weeks.

TRUSOPT contains a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle. After this time there is a greater risk that the drops may become contaminated and cause an eye infection. A new bottle should be opened.

If your doctor tells you to stop using the eye drops or they have passed their expiry date, ask your pharmacist what to do with any remaining solution.

Product description

What does it look like

TRUSOPT comes as eye drops in a 5 mL bottle.

Ingredients

Active ingredient:

- dorzolamide hydrochloride, equivalent to dorzolamide 2%

Inactive ingredients:

- hydroxyethylcellulose
- mannitol
- sodium citrate
- sodium hydroxide
- benzalkonium chloride as preservative

Marketing Authorization Holder

Mundipharma Pty Limited, located at 88 Phillip Street, Sydney NSW
2000 Australia

Manufacturer:

Laboratoires Merck Sharp & Dohme-Chibret
Route de Marsat, RIOM 63963
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