TRUSAMIDE

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using TRUSAMIDE, speak to your doctor or pharmacist.

1. Why am I using TRUSAMIDE?

TRUSAMIDE contains the active ingredient dorzolamide hydrochloride. TRUSAMIDE is used to lower raised pressure in the eye and to treat ocular hypertension or open-angle glaucoma.

For more information, see Section 1. Why am I using TRUSAMIDE? in the full CMI.

2. What should I know before I use TRUSAMIDE?

Do not use if you have ever had an allergic reaction to TRUSAMIDE or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or breastfeeding or plan to become pregnant or breastfeed..

For more information, see Section 2. What should I know before I use TRUSAMIDE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TRUSAMIDE and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use TRUSAMIDE?

- Your doctor will tell you how many drops you need to use each day.
- The usual dose for adults is one drop three times a day, in either one or both eyes.
- Remove soft contact lenses before using the eye drops and wait 15 minutes before putting them back in.
- Tilt your head back, pull down the lower eyelid, look up, and squeeze one drop into the eye. Release the eyelid, close the eye without blinking, and press the inner corner against your nose for about two minutes.

More instructions can be found in Section 4. How do I use TRUSAMIDE? in the full CMI.

5. What should I know while using TRUSAMIDE?

Things you must do	• Remind any doctor, dentist or pharmacist you visit that you are using TRUSAMIDE. • To make sure TRUSAMIDE is working properly, have your eye pressure checked regularly. • Tell your doctor if you develop an eye infection, receive an eye injury, or have eye surgery. • Tell your doctor if you become pregnant while using TRUSAMIDE.
Things you must not do	• Do not give TRUSAMIDE to anyone else, even if they have the same condition or symptoms as you. • Do not stop using TRUSAMIDE without first talking to your doctor.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how TRUSAMIDE affects you. it may cause certain side effects in some people, including blurred vision and dizziness.
Looking after your medicine	• Keep your eye drops below 30°C and away from light. Discard four weeks after opening. • Do not store the bathroom, near a sink, in the car, window sills or on in your clothes pockets . • Do not leave the cap off the bottle for any length of time to avoid contaminating the eye drops.

For more information, see Section 5. What should I know while using TRUSAMIDE? in the full CMI.

6. Are there any side effects?

Less serious side effects are eye problems, feeling sick, bitter taste, dry mouth, nose bleeds, throat irritation, headache, dizziness, tiredness, weakness, kidney stones, numbness or tingling in fingers or toes. Serious side effects are 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 nettlerash, skin rash, itchiness. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

TRUSAMIDE

Active ingredient(s): *Dorzolamide hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TRUSAMIDE. **Speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TRUSAMIDE.**

Where to find information in this leaflet:

1. Why am I using TRUSAMIDE?
2. What should I know before I use TRUSAMIDE?
3. What if I am taking other medicines?
4. How do I use TRUSAMIDE?
5. What should I know while using TRUSAMIDE?
6. Are there any side effects?
7. Product details

1. Why am I using TRUSAMIDE?

TRUSAMIDE contains the active ingredient dorzolamide hydrochloride. TRUSAMIDE belongs to a family of medicines called carbonic anhydrase inhibitors. TRUSAMIDE lowers pressure in the eye by reducing the production of fluid.

TRUSAMIDE is used to lower raised pressure in the eye to treat ocular hypertension or open-angle 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 TRUSAMIDE helps control your glaucoma it does not cure it.

For more information about glaucoma, contact Glaucoma Australia Inc., PO Box 420, Crows Nest 1585, telephone 1800 500 880.

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

TRUSAMIDE is not addictive.

2. What should I know before I use TRUSAMIDE?

Warnings

Do not use TRUSAMIDE if:

- you are allergic to dorzolamide hydrochloride, or any of the ingredients listed at the end of this leaflet

  Always check the ingredients to make sure you can use this medicine.
- you have severe kidney disease
- you are breastfeeding or plan to breastfeed

  It is not known whether TRUSAMIDE passes into breast milk.
- the seal around the cap is broken
- the bottle shows signs of tampering
- the expiry date on the pack has passed.

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

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

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

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

Check with your doctor if you:

- have or have had any of the following medical conditions:
  - kidney disease, including a history of kidney stones
  - liver disease
- take any medicines for any other condition
- you have an allergy to sulfonamide medicines

  The active ingredient of TRUSAMIDE, dorzolamide hydrochloride, is a sulfonamide related compound. Therefore, if you are allergic to sulfonamide medicines you may be allergic to TRUSAMIDE. Check with your doctor or pharmacist if you are not sure whether you are allergic to sulfonamides.
- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes
- you have any eye conditions including dry eyes.

The preservative (benzalkonium chloride) in TRUSAMIDE may cause eye irritation, dry eye symptoms, and may affect some structures in the eye.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or plan to become pregnant.

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

Tell your doctor if you are breastfeeding or plan to breastfeed.

Use in children

Do not give TRUSAMIDE to a child.

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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

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

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

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TRUSAMIDE.

4. How do I use TRUSAMIDE?

How much to use

- Your doctor will tell you how many drops you need to use each day.
- When TRUSAMIDE 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 TRUSAMIDE with a betablocker eye drop, then the usual dose for adults is one drop of TRUSAMIDE twice a day, in either one or both eyes.
- **Use TRUSAMIDE only when prescribed by your doctor.**
- Follow all directions given to you by your doctor carefully.

  They may differ from the information contained in this leaflet.

When to use TRUSAMIDE

- If you are using TRUSAMIDE 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 TRUSAMIDE twice a day, use the drops in the morning and in the evening (i.e. approximately 12 hours apart).
- **Use TRUSAMIDE 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 TRUSAMIDE

- **Before opening the bottle for the first time, make sure the two safety seals joining the cap to the bottle are not broken. If they are, 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.**

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

Instructions:

1. Wash your hands well with soap and water.
2. To open the bottle for the first time, hold the bottle upright and turn the cap in the direction of the arrows until you can lift it off. This will break the two safety seals.
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.
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

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

If you forget to use TRUSAMIDE

If it is almost time for your next dose, skip the dose you missed and take 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 take a double dose to make up for the dose you missed.

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

If you use too much TRUSAMIDE

If you think that you or anyone else may have swallowed any or all of the contents of a bottle of TRUSAMIDE, or used too many drops, urgent medical attention may be needed.

Symptoms may include feeling drowsy, nauseous, light-headed or dizzy.

You should immediately:

- phone the Poisons Information Centre **(by calling 13 11 26)** for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using TRUSAMIDE?

Things you must do

- To make sure TRUSAMIDE is working properly, have your eye pressure checked regularly at the times your eye specialist recommends.

Call your doctor straight away 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 TRUSAMIDE because of possible contamination of the old one, or may advise you to stop your treatment with TRUSAMIDE.
- become pregnant while using TRUSAMIDE.
- are about to be started on any new medicine, tell your doctor and pharmacist that you are using TRUSAMIDE.

Tell doctor, dentist or pharmacist you visit that you are using TRUSAMIDE.

Things you must not do

- Do not give TRUSAMIDE to anyone else, even if they have the same condition as you or their symptoms seem similar.
- Do not stop using TRUSAMIDE 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TRUSAMIDE affects you.

TRUSAMIDE 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 TRUSAMIDE before you drive a car or operate machinery.

Looking after your medicine

- Keep your eye drops below 30°C.
- Keep the eye drops away from light.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.
- in the pockets of your clothes.

Heat and dampness can destroy some medicines.

Keep it where young 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.

When to dispose of your medicine

- **Dispose of TRUSAMIDE four weeks after opening.**

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

  TRUSAMIDE 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 you no longer need to use it
- After the expiry date (if unopened) or four weeks after opening.
- The tamper evident seal has been damaged when you receive it

Getting rid of any unwanted medicine

Take it to any pharmacy for safe disposal.

6. Are there any side effects?

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

TRUSAMIDE 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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

Less serious side effects

Less serious side effects	What to do
• 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, irritation or feeling of having something in the eye, dry eyes • feeling sick • bitter taste, dry mouth • nose bleeds • throat irritation • headache, dizziness • tiredness, weakness • kidney stones	**Speak to your doctor if you have any of these less serious side effects.**
• numbness or tingling in fingers or toes.	

Serious side effects

Serious side effects	What to do
• 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 nettlerash • skin rash, itchiness	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

TRUSAMIDE is only available with a doctor's prescription.

What TRUSAMIDE contains

Active ingredient (main ingredient)	dorzolamide hydrochloride, equivalent to dorzolamide 2%
Other ingredients (inactive ingredients)	hydroxyethylcellulose mannitol sodium citrate sodium hydroxide benzalkonium chloride as preservative

Do not take this medicine if you are allergic to any of these ingredients.

What TRUSAMIDE looks like

TRUSAMIDE eye drops come in a plastic bottle. The drops are a clear, slightly viscous, colorless aqueous solution (AUST R 217251).

TRUSAMIDE comes as eye drops in a 5 mL bottle

Who distributes TRUSAMIDE

Alphapharm Pty Ltd trading as Viatris
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

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