

# Dithiazide™ 25 mg Tablets

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Dithiazide 25 mg Tablets?

Dithiazide contains the active ingredient hydrochlorothiazide. Dithiazide is used to treat high blood pressure. For more information, see Section [1. Why am I using Dithiazide?](#) in the full CMI.

### 2. What should I know before I use Dithiazide 25 mg Tablets?

Do not use if you have ever had an allergic reaction to hydrochlorothiazide 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 plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use Dithiazide?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Dithiazide 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 Dithiazide 25 mg Tablets?

**Adults:** For blood pressure 25 mg or 50 mg once daily or in divided dose and mostly between 12.5 mg to 100 mg per day. For oedema 25 mg to 100 mg once daily or twice daily. **Infants and children:** Based on age and body weight the doctor will decide the dose. More instructions can be found in Section [4. How do I use Dithiazide?](#) in the full CMI.

### 5. What should I know while using Dithiazide 25 mg Tablets?

<b>Things you should do</b>	<ul style="list-style-type: none"> <li>Remind any doctor, surgeon, anaesthetist, dentist, pharmacist or nurse that you visit that you are taking Dithiazide.</li> <li>If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Dithiazide.</li> <li>If you become pregnant while taking Dithiazide, tell your doctor immediately.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>Do not lower the dosage or stop your medicine unless instructed by your doctor.</li> <li>Do not use your medicine to treat any other complaints of yours or others.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>Be careful driving or operating machinery as Dithiazide may cause dizziness or light-headedness.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>Drinking alcohol may cause dizziness and light-headedness.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>Store below 25<sup>0</sup>C in the bottle where children cannot reach it.</li> </ul>

For more information, see Section [5. What should I know while using Dithiazide?](#) in the full CMI.

### 6. Are there any side effects?

**Common side effects** include numbness/tingling in hands and feet, muscle spasm, restlessness, dizziness, headache, vomiting, nausea, loss of appetite, stomach cramps, diarrhoea or constipation, fever, weakness, sore saliva glands. **Serious side effects** include blurred, decreased or yellow vision, eye pain due to changes in blood pressure; signs of anaemia, nose bleeds; allergic skin rash, itching, hives, unusual bleeding or bruising under the skin, purple or red spots visible through the skin, blister formation, peeling of layers of skin, dry skin, lesion or sore on the lips or skin that does not heal, swelling of the face, lips, tongue or other parts of the body, severe skin reactions, sensitivity to sunlight; stomach pain, vomiting, jaundice; signs of gout, aching muscles, generally feeling unwell; fast heartbeat; fever, severe chills, sore throat or mouth ulcers; changes in amount of urine passed, red coloured urine; excessive thirst, dry mouth; coughing, difficulty breathing, wheezing. 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.

# Dithiazide™ 25 mg Tablets

**Active ingredient:** *Hydrochlorothiazide*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Dithiazide. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Dithiazide.**

**Where to find information in this leaflet:**

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

### 1. Why am I using Dithiazide 25 mg Tablets?

Dithiazide contains the active ingredient **hydrochlorothiazide**. Dithiazide belongs to a group of medicines called diuretics.

**Dithiazide is used to treat**

- high blood pressure which is also called hypertension.
- the build-up of fluid in the body which may cause swelling. This is called oedema and can occur as the result of some heart, lung or kidney conditions.
- fluid build-up caused by pre-menstrual tension (PMT) or certain medications.

This medicine may be taken alone or in combination with other medicines to treat your condition.

It helps reduce the amount of excess fluid in the body by increasing the amount of urine produced. This helps reduce some forms of swelling and fluid accumulation and reduce high blood pressure.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

### 2. What should I know before I use Dithiazide 25 mg Tablets?

#### Warnings

**Do not use Dithiazide if you are allergic to:**

- hydrochlorothiazide, or any of the ingredients listed at the end of this leaflet

- medicines which contain sulfur, such as sulfur antibiotics or some medicines used to treat diabetes.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Always check the ingredients to make sure you can use this medicine.

Do not take this medicine if you are unable to produce or pass urine.

**Check with your doctor if you:**

- have allergies to any other medicines, foods, preservatives or dyes
- have experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past.
- have or have had any of the following medical conditions:
  - liver problems or chronic liver disease
  - kidney problems
  - unusual amount of salt in the body
  - high cholesterol levels
  - diabetes
  - gout
  - difficulty passing urine
  - systemic lupus erythematosus (SLE), a disease affecting the skin, joints and kidneys.

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

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

The active ingredient in Dithiazide passes into breast milk and there is a possibility that your baby may be affected.

### 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 interfere with Dithiazide and affect how it works.**

These include:

- medicines used to treat high blood pressure and some other heart conditions
- other thiazide diuretics used to reduce swelling and increase fluid loss
- pressor amines such as adrenaline
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- medicines used to relax muscles before or during surgery
- steroid medicines such as cortisone, prednisone and dexamethasone
- lithium, a medicine used to treat mood swings and some types of depression
- barbiturates, medicines used to treat epilepsy, to produce calmness or to help you sleep
- narcotic/strong pain killers, such as codeine, morphine and dextropropoxyphene
- insulin and tablets used to treat diabetes
- cholestyramine and colestipol resins, medicines used to treat high blood cholesterol levels
- alcohol

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

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

## 4. How do I use Dithiazide 25 mg Tablets?

### How much to take

- Your doctor will tell you how many tablets you will need to take each day.
  - For high blood pressure, the usual adult starting dose is 25 mg or 50 mg a day, taken as a single dose or in divided doses. Some patients may be started on a lower dose. Depending on how you respond, the dose may need to be increased. Most patients take between 12.5 mg to 100 mg each day.
  - For oedema, the usual adult dose is 25 mg to 100 mg, once or twice a day.
  - Infants and children: Your doctor will tell you the dose. This is based on age and body weight.
  - PMT related oedema: This medicine helps lower the build-up of fluid in your body, which can occur before the start of your menstrual period. Therefore, you should take Dithiazide from the start of your symptoms until the onset of your period.

Follow the instructions provided and use Dithiazide until your doctor tells you to stop.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

### When to take Dithiazide 25 mg Tablets

- Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take it.
- If you are taking Dithiazide once a day, this is best in the morning, for example, at breakfast time.
- If you are taking Dithiazide more than once a day, take your first dose immediately after breakfast and take your last dose no later than 6pm, unless your doctor tells you otherwise.
- Dithiazide may increase the amount of urine you pass and the number of times you need to go to the toilet. By taking your last dose no later than 6 pm there may be less chance that your sleep is disturbed.

### How to take Dithiazide 25 mg Tablets

Swallow the tablet/s whole with a full glass of water.

### If you forget to use Dithiazide 25 mg Tablets

Dithiazide should be taken at about the same time each day unless your doctor tells you otherwise. If you miss your dose at the usual time and not sure what to do ask your doctor or pharmacist.

**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, take it as soon as you remember, and then go back to taking your medicine as you would normally.

**Do not take a double dose to make up for the dose you missed.**

If you have trouble remembering to take your medicine, ask your doctor or pharmacist for some hints.

### If you use too much Dithiazide 25 mg Tablets

If you think that you have used too much Dithiazide, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), 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 Dithiazide 25 mg Tablets?

### Things you should do

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Dithiazide.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of these tests.

Have your blood pressure checked when your doctor says, to make sure this medicine is working properly.

Have regular skin cancer checks. Treatment with Dithiazide particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer).

Tell your doctor if you have excessive vomiting or diarrhoea or experience any of the following symptoms:

- dry mouth or thirst
- weakness, tiredness or drowsiness
- muscle pain or cramps
- fast heartbeat
- passing less urine than normal.

If you experience these symptoms, you may be dehydrated because you are losing too much water. Make sure you drink enough water during exercise and hot weather when you are taking this medicine, especially if you sweat a lot.

If you do not drink enough water while taking this medicine, you may feel faint, light-headed or sick. This is because your blood pressure is dropping suddenly, and you are dehydrating. If you continue to feel unwell, tell your doctor.

**Call your doctor straight away if you:**

- become pregnant during the course of treatment with Dithiazide
- develop any severe shortness of breath or difficulty breathing after taking Dithiazide. Seek medical attention immediately.

Remind any doctor, dentist, pharmacist or nurse you visit that you are using Dithiazide.

**Things you should not do**

- Do not stop taking this medicine suddenly.
- Do not take Dithiazide to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or lower the dosage, without checking with your doctor.

**Driving or using machines**

**Be careful driving or operating any machinery or tools until you know how Dithiazide affects you.**

Dithiazide may cause dizziness or light-headedness in some people. If you have any of these symptoms, do not drive,

operate machinery or do anything else that could be dangerous.

**Drinking alcohol**

**Tell your doctor if you drink alcohol.**

Alcohol may worsen your dizziness or lightheadedness.

**Things to be careful of**

If you experience a decrease in vision or eye pain, these could be symptoms of fluid accumulation in the vascular layer of the eye or an increase of pressure in your eye and can happen within hours to a week of taking Dithiazide. This can lead to permanent vision loss if not treated. If you have previously had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.

Protect your skin from sun exposure and UV rays while taking Dithiazide if you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with Dithiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer).

**Looking after your medicine**

- Keep your tablets in the bottle until it is time to take them.
- Keep your tablets in a cool dry place where the temperature stays below 25°C.
- Store Dithiazide away from moisture, heat and sunlight. Do not store Dithiazide or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

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

**Keep it where young children cannot reach it.**

**When to discard your medicine**

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any that are left over.

**Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

**6. Are there any side effects?**

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.

**Less serious side effects**

Less serious side effects	What to do
<p><b>Nervous system:</b></p> <ul style="list-style-type: none"> <li>• numbness or tingling in the hands and/or feet</li> <li>• dizziness, light-headedness or spinning sensation</li> <li>• headache</li> </ul> <p><b>Musculoskeletal:</b></p> <ul style="list-style-type: none"> <li>• muscle spasm, pains or cramps</li> <li>• weakness</li> <li>• restlessness</li> </ul> <p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"> <li>• vomiting, nausea</li> <li>• loss of appetite</li> <li>• stomach cramps,</li> <li>• diarrhoea or constipation</li> <li>• sore saliva glands.</li> </ul> <p><b>Infection:</b></p> <ul style="list-style-type: none"> <li>• Fever</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

**Serious side effects**

Serious side effects	What to do
<p><b>Eye related:</b></p> <ul style="list-style-type: none"> <li>• blurred vision or yellow vision</li> <li>• decrease in vision or eye pain due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye or acute angle- closure glaucoma)</li> </ul> <p><b>Haematological:</b></p> <ul style="list-style-type: none"> <li>• signs of anaemia such as tiredness, shortness of breath when exercising, dizziness and looking pale</li> <li>• bleeding or bruising more than normal</li> <li>• nose bleeds</li> </ul> <p><b>Skin related:</b></p> <ul style="list-style-type: none"> <li>• sudden allergic rash, itching, hives or nettle rash (pinkish, itchy swelling on the skin)</li> <li>• unusual bleeding or bruising under the skin</li> <li>• purple or red spots visible through the skin</li> <li>• dry skin</li> <li>• lesion or sore on the lips or skin that does not heal</li> </ul>	<p><b>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.</b></p>

<ul style="list-style-type: none"> <li>• swelling of the face, lips, tongue or other parts of the body</li> <li>• severe skin reaction starting as painful red areas, then large blisters and ending with peeling of layers of skin</li> <li>• increased sensitivity to sunlight</li> </ul> <p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"> <li>• severe stomach pain, often with nausea or vomiting</li> <li>• yellowing of the skin and/or eyes, also called jaundice</li> </ul> <p><b>Musculoskeletal:</b></p> <ul style="list-style-type: none"> <li>• signs of gout such as painful swollen joints</li> <li>• aching muscles</li> <li>• feeling unwell</li> </ul> <p><b>Cardiovascular related:</b></p> <ul style="list-style-type: none"> <li>• fast heartbeat</li> </ul> <p><b>Infection that appears frequently</b></p> <ul style="list-style-type: none"> <li>• fever</li> <li>• severe chills</li> <li>• sore throat or mouth ulcers</li> </ul> <p><b>Urinary tract related:</b></p> <ul style="list-style-type: none"> <li>• changes in amount of urine passed (too little, none or large amounts)</li> <li>• red coloured urine</li> </ul> <p><b>Mouth related:</b></p> <ul style="list-style-type: none"> <li>• excessive thirst</li> <li>• dry mouth</li> </ul> <p><b>Respiratory*:</b></p> <ul style="list-style-type: none"> <li>• coughing</li> <li>• difficulty breathing</li> <li>• wheezing</li> <li>• breathlessness</li> <li>• acute respiratory distress is a very rare, but possible side effect. Signs include severe shortness of breath, fever, weakness and confusion. *symptoms may be very severe and usually worsens on lying down</li> </ul>	
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**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](http://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

This medicine is only available with a doctor's prescription.

### What Dithiazide 25 mg Tablets contains

<b>Active ingredient (main ingredient)</b>	hydrochlorothiazide 25 mg/tablet
<b>Other ingredients (inactive ingredients)</b>	lactose monohydrate calcium hydrogen phosphate dihydrate maize starch sunset yellow FCF aluminium lake magnesium stearate
<b>Potential allergens</b>	sugars as lactose

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

Dithiazide 25 mg Tablets do not contain sucrose, gluten or tartrazine.

### What Dithiazide 25 mg Tablets looks like

Dithiazide 25 mg tablets are round, light orange, flat face, bevelled edge tablets bisected on one side, debossed '2083' above the bisect and TEVA debossed on the other side (AUST R 92060).

Dithiazide is supplied in a bottle containing 100 tablets.

### Who distributes Dithiazide 25 mg Tablets

Dithiazide is supplied in Australia by:

Phebra Pty Ltd.

19 Orion Road,

Lane Cove West, NSW 2066, Australia.

Telephone: 1800 720 020

This leaflet was prepared in September 2022

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