

# APO-CANDESARTAN HCTZ

## 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 taking APO-CANDESARTAN HCTZ?

APO-CANDESARTAN HCTZ contains the active ingredients candesartan cilexetil and hydrochlorothiazide.

APO-CANDESARTAN HCTZ is used to treat high blood pressure.

For more information, see Section [1. Why am I taking APO-CANDESARTAN HCTZ?](#) in the full CMI.

### 2. What should I know before I take APO-CANDESARTAN HCTZ?

Do not take if you have ever had an allergic reaction to any medicine containing candesartan cilexetil or 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 take APO-CANDESARTAN HCTZ?](#) in the full CMI.

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

Some medicines may interfere with APO-CANDESARTAN HCTZ 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 take APO-CANDESARTAN HCTZ?

- APO-CANDESARTAN HCTZ should be taken once daily with a glass of water, at about the same time each day.
- It does not matter whether you take APO-CANDESARTAN HCTZ tablets with food or on an empty stomach.

More instructions can be found in Section [4. How do I take APO-CANDESARTAN HCTZ?](#) in the full CMI.

### 5. What should I know while taking APO-CANDESARTAN HCTZ?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Call your doctor straight away if you become pregnant or plan to become pregnant while you are taking APO-CANDESARTAN HCTZ.</li><li>• If you develop any severe shortness of breath or difficulty breathing after taking APO-CANDESARTAN HCTZ, seek medical attention immediately.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking APO-CANDESARTAN HCTZ unless you have discussed it with your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how APO-CANDESARTAN HCTZ affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Alcohol may interfere with APO-CANDESARTAN HCTZ.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep it in a cool, dry place where the temperature stays below 25°C.</li><li>• Keep your tablets in the blister pack until it is time to take them.</li></ul>

For more information, see Section [5. What should I know while taking APO-CANDESARTAN HCTZ?](#) in the full CMI.

### 6. Are there any side effects?

Less serious side effects are headache or dizziness, flu-like symptoms or infections, chest, throat or sinus infections, feeling sick (nausea) or vomiting, back pain, urinary tract infection, feeling tired, stomach ache, symptoms of sunburn which happens more quickly than normal.

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.

# APO-CANDESARTAN HCTZ

Active ingredient(s): *Candesartan cilexetil and Hydrochlorothiazide*

## Consumer Medicine Information (CMI)

This leaflet provides important information about taking APO-CANDESARTAN HCTZ. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking APO-CANDESARTAN HCTZ.**

Where to find information in this leaflet:

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

## 1. Why am I taking APO-CANDESARTAN HCTZ?

APO-CANDESARTAN HCTZ contains the active ingredients candesartan cilexetil and hydrochlorothiazide.

APO-CANDESARTAN HCTZ is used to treat high blood pressure.

Candesartan cilexetil is a type of medicine called an angiotensin-II receptor antagonist (or blocker). It mainly works by causing relaxation of blood vessels.

Hydrochlorothiazide is a type of medicine called a diuretic. It works by reducing the amount of excess fluid in the body.

Taking these two medicines together will lower your blood pressure more than using either one on its own.

## 2. What should I know before I take APO-CANDESARTAN HCTZ?

### Warnings

**Do not take APO-CANDESARTAN HCTZ if:**

- you are allergic to any medicine containing candesartan cilexetil or hydrochlorothiazide, or any of the ingredients listed at the end of this leaflet or any medicine containing an angiotensin II receptor antagonist (or blocker), or any sulphur drugs (sulphonamides) such as some antibiotics or some medicines to treat diabetes. Always check the ingredients to make sure you can use this medicine.
- you have gout.

- you have severe kidney or liver disease and/or conditions associated with impaired bile flow (cholestasis).
- you are taking blood pressure medicine containing aliskiren, especially if you have diabetes mellitus or have kidney problems.
- the packaging is torn or shows signs of tampering.
- the expiry date on the pack has passed.

### Check with your doctor if you:

- have allergies to any other medicines or foods.
- have any of the following medical conditions:
  - Kidney problems.
  - Liver problems.
  - Heart problems.
  - Diabetes.
  - Recent excessive vomiting or diarrhoea.
  - Systemic Lupus Erythematosus (SLE), a disease affecting the skin, joints and kidneys.
  - A salt restricted diet.
  - A condition called primary hyperaldosteronism.
  - A past operation known as sympathectomy.
  - A decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking APO-CANDESARTAN HCTZ. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulphonamide allergy, you can be at higher risk of developing this.
- experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past.
- have any questions about how you should be taking APO-CANDESARTAN HCTZ.

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

**Do not take APO-CANDESARTAN HCTZ if you are pregnant or are planning to become pregnant.**

It may affect your baby if you take it during pregnancy.

**Do take APO-CANDESARTAN HCTZ if you are breastfeeding.**

Your baby can take in components of APO-CANDESARTAN HCTZ from breast milk if you are breastfeeding.

### Use in children

Do not give APO-CANDESARTAN HCTZ to children. There is no information about its use in children.

### 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 and APO-CANDESARTAN HCTZ may interfere with each other. These include:

- Other blood pressure lowering medicines, particularly diuretics (fluid tablets) and ACE inhibitors, especially if you have diabetes-related kidney problems.
- Medicines containing potassium, including salt substitutes.
- Digoxin, a medicine used to treat heart failure.
- Non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis.
- Colestipol and cholestyramine, medicines used to treat high blood cholesterol levels.
- Lithium, a medicine used to treat mood swings and some types of depression.
- Alcohol.
- Strong pain killers such as codeine, morphine, dextropropoxyphene.
- Barbiturates, such as phenobarbitone.
- Medicines like insulin that are used to treat diabetes.
- Calcium supplements, or medicines containing calcium.
- Vitamin D supplements.
- Medicines to treat irregular heart beats.
- Corticosteroids such as prednisone, cortisone, dexamethasone.
- Laxatives.
- Medicines used to treat cancer such as cyclophosphamide.
- Methotrexate, a medicine used to treat arthritis and some cancers.
- Amantadine, a medicine used to treat Parkinson's disease.
- Ciclosporin.

These medicines may be affected by APO-CANDESARTAN HCTZ or may affect how it works. You may need different amounts of your medicines, or 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 APO-CANDESARTAN HCTZ.**

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

### 4. How do I take APO-CANDESARTAN HCTZ?

#### How much to take

- The usual dose is one tablet once daily, taken whole with a glass of water.

#### When to take

**APO-CANDESARTAN HCTZ should be taken once daily, at about the same time each day.**

Keeping a regular time for taking APO-CANDESARTAN HCTZ will help to remind you to take it.

It does not matter whether you take APO-CANDESARTAN HCTZ tablets with food or on an empty stomach.

#### How long to take

APO-CANDESARTAN HCTZ helps control your condition, but does not cure it. Therefore you must take APO-CANDESARTAN HCTZ every day.

Continue taking APO-CANDESARTAN HCTZ for as long as your doctor tells you to.

#### If you forget to take APO-CANDESARTAN HCTZ

If you forget to take a dose, take it as soon as you remember, as long as it is at least 12 hours before your next dose is due.

Then go back to taking it as you would normally.

**If it is less than 12 hours to your next dose, skip the dose you missed and take your next dose when you are meant to.**

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

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

#### If you take too much APO-CANDESARTAN HCTZ

If you think that you have taken too many APO-CANDESARTAN HCTZ tablets, 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.**

If you take too many APO-CANDESARTAN HCTZ tablets, you may get a headache, feel sick (nausea), dizzy, thirsty and very tired.

### 5. What should I know while taking APO-CANDESARTAN HCTZ?

#### Things you should do

- Take APO-CANDESARTAN HCTZ exactly as your doctor has told you to.

Your blood pressure will not be well controlled if you do not.

- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking APO-CANDESARTAN HCTZ.**

- **Tell your doctor if you have excessive vomiting or diarrhoea while taking APO-CANDESARTAN HCTZ.**

You may lose too much water and your blood pressure may become too low.

- **If you plan to have surgery (even at the dentist) that needs a general anaesthetic; tell your doctor or dentist that you are taking APO-CANDESARTAN HCTZ.**
- **Tell your doctor if you plan to have an examination such as an X-ray or a scan requiring an injection of iodinated contrast (dye) that you are taking APO-CANDESARTAN HCTZ.**
- **If you have had skin cancer or if you develop a suspicious skin lesion during treatment with APO-CANDESARTAN HCTZ, tell your doctor or pharmacist.**

Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Limit exposure to sunlight and protect your skin when exposed to sun while taking APO-CANDESARTAN HCTZ.

- **If you develop any severe shortness of breath or difficulty breathing after taking APO-CANDESARTAN HCTZ, seek medical attention immediately.**
- Remind any doctor, dentist or pharmacist you visit that you are taking APO-CANDESARTAN HCTZ.
- **Be sure to keep all of your doctor's appointments so that your progress can be checked.**  
Your doctor will check your progress and may want to take some tests (e.g. blood tests, blood pressure) from time to time. These tests may help to prevent side effects.

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

- become pregnant or plan to become pregnant while taking APO-CANDESARTAN HCTZ. You should not use APO-CANDESARTAN HCTZ if you are pregnant or thinking about becoming pregnant. Your doctor can discuss different treatment options with you.

#### **Things you should not do**

- Do not take APO-CANDESARTAN HCTZ to treat any other conditions unless your doctor says to.
- Do not give APO-CANDESARTAN HCTZ to anyone else, even if they have symptoms that seem similar to yours.
- Do not stop taking APO-CANDESARTAN HCTZ unless you have discussed it with your doctor.

#### **Things you should be careful of**

- Move slowly when getting out of bed or standing up if you feel faint, dizzy or light-headed.
- Drink plenty of water while you are taking APO-CANDESARTAN HCTZ, especially if you sweat a lot.

Talk to your doctor or pharmacist about these possibilities if you think they may bother you.

#### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how APO-CANDESARTAN HCTZ affects you.**

APO-CANDESARTAN HCTZ may cause dizziness when you start taking it due to the drop in your blood pressure.

#### **Drinking alcohol**

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

Alcohol may interfere with APO-CANDESARTAN HCTZ.

#### **Looking after your medicine**

- Keep your tablets in the blister pack until it is time to take them.
- If you take APO-CANDESARTAN HCTZ out of the blister pack it will not keep well.
- Keep it in a cool, dry place where the temperature stays below 25°C.

Follow the instructions on 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.

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

#### **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.

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking APO-CANDESARTAN HCTZ.**

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**

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Headache or dizziness.</li> <li>• Chest, throat or sinus infection.</li> <li>• Flu-like symptoms or infections.</li> <li>• Feeling sick (nausea) or vomiting.</li> <li>• Back pain.</li> <li>• Urinary tract infection.</li> <li>• Feeling tired.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• Stomach ache.</li> <li>• Symptoms of sunburn which happens more quickly than normal.</li> </ul>	

### Serious side effects

Serious side effects	What to do
<p><b>Allergic reaction:</b></p> <ul style="list-style-type: none"> <li>• Swelling of the face, lips, tongue or throat.</li> <li>• Swelling of the hands, feet or ankles.</li> <li>• Rash, itching or hives.</li> </ul> <p><b>Others:</b></p> <ul style="list-style-type: none"> <li>• Rapid heartbeats.</li> <li>• Aching muscles, tenderness or weakness in the muscles.</li> <li>• Suspicious skin lesions.</li> <li>• Harsh sounds when breathing.</li> <li>• Easy bruising or bleeding more easily than normal.</li> <li>• Feel extremely tired.</li> <li>• Yellowing of the skin and/or eyes.</li> <li>• Signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers.</li> <li>• Worsening of kidney function including passing little or no urine, drowsiness, nausea, vomiting, breathlessness, loss of appetite and weakness (especially in patients with existing kidney problems or heart failure).</li> <li>• Changes in your potassium, sodium and red or white blood cell levels may occur. Such changes are usually detected by a blood test.</li> <li>• Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma).</li> <li>• Symptoms that may indicate high potassium levels in the blood include nausea, diarrhoea, muscle weakness and changes in heart rhythm.</li> <li>• Acute respiratory distress (very rare): signs include severe shortness of breath, fever, weakness and confusion.</li> </ul>	<p><b>Stop taking APO-CANDESARTAN HCTZ and 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> <p>You may need urgent medical attention. Serious side effects are rare.</p>

**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 APO-CANDESARTAN HCTZ contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"> <li>• Candesartan cilexetil 16 mg or 32 mg.</li> <li>• Hydrochlorothiazide 12.5 mg or 25 mg.</li> </ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• Lactose monohydrate.</li> <li>• Carmellose calcium.</li> <li>• Maize starch.</li> <li>• Macrogol 8000.</li> <li>• Hyprollose.</li> <li>• Magnesium stearate.</li> <li>• Pigment Blend PB-24880 Pink (PI 108327) (16 mg/12.5 mg and 32 mg/25 mg tablets).</li> <li>• Pigment Blend PB-52290 Yellow (PI 108950) (32 mg/12.5 mg tablet).</li> </ul>
<b>Potential allergens</b>	APO-CANDESARTAN HCTZ contains sugars as lactose.

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

### What APO-CANDESARTAN HCTZ looks like

#### APO-CANDESARTAN HCTZ 16/12.5

Each tablet is light pink, oval shape, biconvex, uncoated, mottled tablets debossed with 'L3' and '02' on either side of breakline on one side and break line on other side.

AUST R 210565.

#### APO-CANDESARTAN HCTZ 32/12.5

Each tablet is light yellow, oval biconvex uncoated mottled tablets debossed with 'L3' & '04' on either side of break line on one side & break line on one other side.

AUST R 210566.

**APO-CANDESARTAN HCTZ 32/25**

Each tablet is light pink, oval biconvex uncoated mottled tablets debossed with 'L3' & '04' on either side of break line on one side & break line on one other side.

AUST R 210567.

Each pack contains 30 tablets.

**Who distributes APO-CANDESARTAN HCTZ**

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel St

Cremorne VIC 3121

Australia

[www.arrotex.com.au](http://www.arrotex.com.au)

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