

# ATACAND PLUS®

## 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 ATACAND PLUS?

ATACAND PLUS contains the active ingredients candesartan cilexetil and hydrochlorothiazide. ATACAND PLUS is used to treat high blood pressure also called hypertension. For more information, see Section [1. Why am I using ATACAND PLUS?](#) in the full CMI.

### 2. What should I know before I use ATACAND PLUS?

Do not use if you have ever had an allergic reaction to ATACAND PLUS or any of the ingredients listed at the end of the CMI, have severe kidney or liver disease and/or conditions associated with impaired bile flow (cholestasis), or are taking blood pressure medicine containing aliskiren and you have diabetes mellitus or kidney problems.

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

For more information, see Section [2. What should I know before I use ATACAND PLUS?](#) in the full CMI.

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

Some medicines may interfere with ATACAND PLUS 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 ATACAND PLUS?

- ATACAND PLUS should be taken once daily, at about the same time each day.
- It does not matter whether you take ATACAND PLUS with food or on an empty stomach.

More instructions can be found in Section [4. How do I use ATACAND PLUS?](#) in the full CMI.

### 5. What should I know while using ATACAND PLUS?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell any doctor, dentist or pharmacist you visit that you are taking ATACAND PLUS.</li><li>• If you develop any severe shortness of breath or difficulty breathing after taking ATACAND PLUS, seek medical attention immediately.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using ATACAND PLUS 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 driving or operating machinery until you know how ATACAND PLUS affects you.</li><li>• You may feel dizzy or weary when you are taking ATACAND PLUS.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li><li>• Drinking alcohol while taking ATACAND PLUS may increase dizziness and light-headedness.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep ATACAND PLUS in a cool, dry place where the temperature stays below 30°C.</li></ul>

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

### 6. Are there any side effects?

Side effects may include headache, dizziness, weariness, chest or throat infection, flu-like symptoms, feeling sick (nausea, vomiting), back pain. Side effects that require urgent medical attention include: Aching muscles, tenderness or weakness in the muscle; swelling of the face, lips, tongue, throat, hands, feet or ankles; harsh sounds when breathing; rash, itching or hives; yellowing of the skin and/or eyes; easy bruising or bleeding more easily than normal; extreme fatigue, tiredness, weakness; signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers; passing little or no urine; awareness of heartbeat; decrease in vision or pain in eyes; new and/or suspicious skin lesions.

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.

# ATACAND PLUS®

Active ingredient: *candesartan cilexetil and hydrochlorothiazide*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ATACAND PLUS. **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 ATACAND PLUS.**

Where to find information in this leaflet:

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

## 1. Why am I using ATACAND PLUS?

ATACAND PLUS contains the active ingredient **candesartan cilexetil and hydrochlorothiazide**. Candesartan cilexetil is a type of medicine called an angiotensin II receptor antagonist (or blocker). Hydrochlorothiazide is a type of medicine called a diuretic.

**ATACAND PLUS is used to treat high blood pressure (also called hypertension).**

ATACAND PLUS lowers blood pressure by dilating (expanding) small blood vessels from the heart and reducing the amount of excess fluid in the body, letting the blood be pumped around the body more easily.

## 2. What should I know before I use ATACAND PLUS?

### Warnings

**Do not use ATACAND PLUS if:**

- you are allergic to candesartan cilexetil, hydrochlorothiazide, or any of the ingredients listed at the end of this leaflet.
- you are allergic to any sulphur drugs (sulphonamides) such as some antibiotics or some medicines to treat diabetes.
- you have severe kidney or liver disease and/or conditions associated with impaired bile flow (cholestasis).
- you are taking blood pressure medicines containing aliskiren and you have diabetes mellitus (type I or II) or kidney problems.

- you have gout.

### Check with your doctor if you:

Have any other medical condition, especially:

- kidney, liver or heart problems.
- a narrowing of the valves which allow blood into or out of the heart (aortic valve stenosis or mitral valve stenosis) or a genetic condition which causes thickening of the walls in the heart called Obstructive Hypertrophic Cardiomyopathy.
- a condition where your adrenal glands produce too much aldosterone, called primary hyperaldosteronism.
- recent excessive vomiting or diarrhoea.
- skin cancers, including non-melanoma skin cancer (NMSC), basal cell carcinoma (BCC) or squamous cell carcinoma (SCC).
- Systemic Lupus Erythematosus (SLE), a disease affecting the skin, joints and kidneys.

Check with your doctor if you are taking any medicines for any other conditions.

Check with your doctor if you:

- are on a salt restricted diet.
- had a past operation known as sympathectomy (a procedure on the sympathetic nerve chain sometimes used to treat excessive sweating, chronic pain, or poor blood flow to the legs).
- have any planned surgeries that may need a general anaesthetic (including dental surgery).

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 use ATACAND PLUS if you are pregnant or planning to become pregnant.**

Discuss with your doctor if you are pregnant or intend to become pregnant. ATACAND PLUS may affect your baby if you take it during pregnancy.

Discuss with your doctor if you are breastfeeding or intend to breastfeed. It is not known if ATACAND PLUS passes into breast milk. Because of its potential to effect the baby, it is not recommended to breastfeed while taking ATACAND PLUS.

### 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 ATACAND PLUS may interfere with each other. These include:**

- Any medicines containing potassium, including salt substitutes.
- Diuretics (fluid tablets).
- Lithium, a medicine used to treat psychiatric conditions such as bipolar disorder or schizoaffective disorder.
- Non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis, such as aspirin, etoricoxib, and celecoxib.
- Medicines used to treat blood pressure, including aliskiren-containing medicines, angiotensin-converting-enzyme (ACE) inhibitors such as enalapril, lisinopril, ramipril, and captopril, and beta-blockers such as metoprolol and propranolol.
- Digoxin or mineralocorticoid receptor antagonists (MRAs), such as spironolactone and eplerenone, medicines used to treat heart failure.
- Colestipol and cholestyramine, medicines used to treat high blood cholesterol levels.
- Heparin, a medicine used to stop blood from clotting.
- Some antibiotics such as trimethoprim/sulfamethoxazole and some anti-fungals such as amphotericin.
- Strong pain killers such as codeine, morphine, oxycodone and dextropropoxyphene.
- Barbiturates, such as phenobarbitone, which are used to prevent seizures.
- Medicines used to treat diabetes, including insulin.
- Calcium supplements or medicines containing calcium.
- Vitamin D supplements.
- Medicines called bile acid sequestrants used to treat high cholesterol (cholestyramine and colestipol hydrochloride).
- Medicines to treat irregular heartbeats such as digoxin.
- Corticosteroids such as prednisone, prednisolone, dexamethasone.
- Laxatives.
- Medicines used to treat cancer such as cyclophosphamide.
- Methotrexate, a medicine used to treat arthritis and some cancers.
- Medicines used for the treatment of Parkinson's disease including amantadine and biperiden.

- Ciclosporin, a medicine used to suppress the immune system.
- Diazoxide, a medicine used to treat low blood sugar.
- Medicines that contain atropine, such as for the treatment of diarrhoea.

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

### 4. How do I use ATACAND PLUS?

#### How much to take

- The usual dose is one tablet once daily.
- Follow the instructions provided and use ATACAND PLUS until your doctor tells you to stop.

#### When to take ATACAND PLUS

- ATACAND PLUS should be taken once a day, at the same time each day. Keeping a regular time for taking ATACAND PLUS will help to remind you to take it.
- It does not matter whether you take ATACAND PLUS with food or on an empty stomach.

#### If you forget to use ATACAND PLUS

ATACAND PLUS should be used regularly at the same time each day. If you miss your dose at the usual time, 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 normally would.

**If it is almost time for 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 use too much ATACAND PLUS

If you think that you or anyone else may have taken too much ATACAND PLUS, 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 ATACAND PLUS?

#### Things you should do

**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.

Remind any doctor, dentist or pharmacist you visit that you are using ATACAND PLUS.

### Things you should not do

- Do not stop using this medicine unless you have discussed it with your doctor.

### Things to be careful of

- Move slowly when getting out of bed or standing up if you feel faint, dizzy or light-headed.
- Tell your doctor if you have excessive vomiting or diarrhoea while taking ATACAND PLUS.
- Make sure you drink enough water while you are taking ATACAND PLUS, especially during exercise and hot weather, or if you sweat a lot.
- Tell your doctor if you plan to have an examination such as an X-ray or a scan requiring and injection of iodinated contrast (dye) that you are taking ATACAND PLUS.
- If you have had skin cancer or if you develop a suspicious skin lesion during treatment with ATACAND PLUS, tell your doctor or pharmacist.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how ATACAND PLUS affects you.**

ATACAND PLUS may cause dizziness or weariness in some people during treatment.

### Drinking alcohol

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

Drinking alcohol while taking ATACAND PLUS may increase dizziness and light-headedness.

### Looking after your medicine

Store ATACAND PLUS below 30°C.

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 windowsills.

**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.

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>General disorders</b></p> <ul style="list-style-type: none"> <li>• Headache</li> <li>• Dizziness</li> <li>• Weariness</li> </ul> <p><b>Infection related</b></p> <ul style="list-style-type: none"> <li>• Chest or throat infection</li> <li>• Flu-like symptoms</li> </ul> <p><b>Stomach (gastrointestinal) related</b></p> <ul style="list-style-type: none"> <li>• Feeling sick (nausea, vomiting)</li> </ul> <p><b>Joint or muscle related</b></p> <ul style="list-style-type: none"> <li>• Back pain</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>Joint or muscle related</b></p> <ul style="list-style-type: none"> <li>• Aching muscles, tenderness or weakness in the muscle</li> </ul> <p><b>Allergy related</b></p> <ul style="list-style-type: none"> <li>• Swelling of the face, lips, tongue throat, hands, feet or ankles</li> <li>• Rash, itching or hives</li> </ul> <p><b>Lung related</b></p> <ul style="list-style-type: none"> <li>• Harsh sounds when breathing</li> </ul> <p><b>Liver related</b></p> <ul style="list-style-type: none"> <li>• Yellowing of the skin and/or eyes</li> </ul> <p><b>Blood related</b></p> <ul style="list-style-type: none"> <li>• Easy bruising or bleeding more easily than normal</li> <li>• Signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers</li> <li>• Extreme fatigue, tiredness, weakness</li> <li>• Nausea, diarrhoea, muscle weakness and awareness of heartbeat</li> </ul> <p><b>Kidney related</b></p> <ul style="list-style-type: none"> <li>• Passing little or no urine, drowsiness, nausea, vomiting, breathlessness, loss of appetite</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>

and weakness (especially in patients with existing kidney problems or heart failure)	
<b>Eye related</b> <ul style="list-style-type: none"> <li>Decrease in vision or pain in your eyes due to high pressure</li> </ul>	
<b>Infection related</b> <ul style="list-style-type: none"> <li>Urinary tract infection</li> </ul>	<b>Make an appointment to speak to your doctor.</b>
<b>Skin related</b> <ul style="list-style-type: none"> <li>New and/or suspicious skin lesions</li> </ul>	

**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 ATACAND PLUS contains

<b>Active ingredient (main ingredient)</b>	candesartan cilexetil hydrochlorothiazide
<b>Other ingredients (inactive ingredients)</b>	Carmellose calcium Hyprolose Iron oxide red Iron oxide yellow Lactose monohydrate Magnesium stearate Maize starch Macrogol 8000

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

### What ATACAND PLUS looks like

ATACAND PLUS 16/12.5 tablets are peach, oval, biconvex tablets with a score on both sides and engraved  $\frac{A}{CS}$ .

ATACAND PLUS 32/12.5 tablets are yellow, oval, biconvex tablets with a score and engraved  $\frac{A}{CJ}$  on one side and a pressure sensitive bisect on the reverse side.

ATACAND PLUS 32/25 tablets are pink, oval, biconvex tablets with a score and engraved  $\frac{A}{CD}$  on one side and a pressure sensitive bisect on the reverse side.

ATACAND PLUS is registered in blister packs\* of 7 or 30 tablets.

\*not all presentations might be available in Australia.

Australian Registration Numbers:

ATACAND PLUS 16/12.5 – AUST R 76646

ATACAND PLUS 32/12.5 – AUST R 154247

ATACAND PLUS 32/25 – AUST R 154251

### Who distributes ATACAND PLUS

Link Medical Products Pty Ltd

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Australia

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linkhealthcare.com.au

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