

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 ingredient candesartan cilexetil and hydrochlorothiazide. ATACAND PLUS is used to treat high blood pressure. For more information, see Section [1. Why I am 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 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 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 with a glass of water, 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?

Things you should do	<ul style="list-style-type: none">• Call your doctor straightaway if you become pregnant or plan to become pregnant while you are taking ATACAND PLUS.• If you develop any severe shortness of breath or difficulty breathing after taking ATACAND PLUS, seek medical attention immediately.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking ATACAND PLUS unless you have discussed it with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how ATACAND PLUS affects you.
Drinking alcohol	<ul style="list-style-type: none">• Alcohol may interfere with ATACAND PLUS.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the blister pack until it is time to take them.• Keep it in a cool, dry place where the temperature stays below 30°C.

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

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. These include headache, nausea, flu-like symptoms, back pain, feeling tired or stomach ache. However, some side effects may need medical attention. These include rapid heartbeats, aching muscles, suspicious skin lesions, passing little urine, loss of appetite, decrease in vision or pain in your eyes or shortness of breath, fever, weakness and confusion. Serious side effects are rare.

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(s): *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 I am 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.

ATACAND PLUS 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.

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

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

Warnings

Do not use ATACAND PLUS 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.**

Check with your doctor if you:

- have any allergies to any other medicines or foods.
- have any of the following medical conditions:

- o kidney problems
- o liver problems
- o heart problems
- o diabetes
- o recent excessive vomiting or diarrhoea
- o Systemic Lupus Erythematosus (SLE), a disease affecting the skin, joints and kidneys
- o a salt restricted diet
- o a condition called primary hyperaldosteronism
- o a past operation known as sympathectomy
- o 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 ATACAND PLUS. 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 using your ATACAND PLUS.

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 are planning to become pregnant.

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

Do not use ATACAND PLUS if you are breastfeeding.

Your baby can take in components of ATACAND PLUS from breast milk if you are breastfeeding.

Use in children

Do not give ATACAND PLUS to children. There is no information about its use in children.

3. What if I am taking other medicines?

Some medicines and ATACAND PLUS 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 ATACAND PLUS 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 ATACAND PLUS.

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

4. How do I use ATACAND PLUS?

How much to take

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

When to take

ATACAND PLUS should be taken once daily, at about 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.

How long to take

ATACAND PLUS helps control your condition, but does not cure it. Therefore, you must take ATACAND PLUS every day. Continue taking the tablets for as long as your doctor tells you to.

If you forget to use ATACAND PLUS

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 use too much ATACAND PLUS

If you think that you have used 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.

If you take too many ATACAND PLUS tablets you may get a headache, feel sick (nausea), dizzy, thirsty and very tired.

5. What should I know while using ATACAND PLUS?

Things you should do

Take ATACAND PLUS 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 ATACAND PLUS.

Tell your doctor if you have excessive vomiting or diarrhoea while taking ATACAND PLUS.

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 ATACAND PLUS.**

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 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.

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 ATACAND PLUS.

If you develop any severe shortness of breath or difficulty breathing after taking ATACAND PLUS, seek medical attention immediately.

Call your doctor straight away if you:

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

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

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.

Things you should not do

- Do not use it to treat any other complaints unless your doctor says to.
- Do not give this medicine to anyone else, even if they have symptoms that seem similar to yours.

- Do not stop taking ATACAND PLUS 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 using ATACAND PLUS, especially if you sweat a lot.**

Please 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 ATACAND PLUS affects you.

ATACAND PLUS 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 ATACAND PLUS.

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them.
- If you take ATACAND PLUS out of the blister pack it will not keep well.
- Keep it in a cool, dry place where the temperature stays below 30°C.

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 ATACAND PLUS.

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
<ul style="list-style-type: none"> • headache or dizziness • flu-like symptoms or infections • chest, throat or sinus infections 	<p>Speak to your doctor if you have any of these less serious side effects and</p>

<ul style="list-style-type: none"> • feeling sick (nausea) or vomiting • back pain • urinary tract infection • feeling tired • stomach ache • symptoms of sunburn which happens more quickly than normal. 	they worry you.
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Serious side effects

Serious side effects	What to do
<p>Allergic Reaction:</p> <ul style="list-style-type: none"> • swelling of the face, lips, tongue or throat • swelling of the hands, feet or ankles • rash, itching or hives <p>Others:</p> <ul style="list-style-type: none"> • rapid heartbeats • aching muscles, tenderness or weakness in the muscles • suspicious skin lesions • harsh sounds when breathing • easy bruising or bleeding more easily than normal • feel extremely tired • yellowing of the skin and/or eyes • signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers • worsening of the 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) • changes in your potassium, sodium and red or white blood cell levels may occur. Such changes are usually detected by a blood test • 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] • symptoms that may indicate high potassium levels in the blood include nausea, diarrhoea, muscle weakness and changes in heart rhythm • acute respiratory distress (very rare): signs include severe shortness of breath, fever, weakness and confusion 	<p>Stop taking ATACAND PLUS 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.</p> <p>You may need urgent medical attention.</p> <p>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. 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 tablet contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">• candesartan cilexetil 16 mg or 32 mg• hydrochlorothiazide 12.5 mg or 25 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Carmellose calcium• Hyprolose• Iron oxide red• Iron oxide yellow• Lactose monohydrate• Magnesium stearate• Maize starch• Macrogol 8000
Potential allergens	Lactose monohydrate

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

ATACAND PLUS does not contain gluten.

What ATACAND PLUS looks like

ATACAND PLUS is available in three different tablet strengths:

- ATACAND PLUS 16/12.5 tablets are peach, oval, biconvex tablets with a score on both sides and marked A/CS. [AUST R 76646]
- ATACAND PLUS 32/12.5 tablets are yellow, oval, biconvex tablets with a score and marked with A/CJ on one side and a pressure sensitive bisect on the reverse side. [AUST R 154247]
- ATACAND PLUS 32/25 tablets are pink, oval, biconvex tablets with a score and marked with A/CD on one side and a pressure sensitive bisect on the reverse side. [AUST R 154251]

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

*not all presentations might be available in Australia

Who distributes ATACAND PLUS

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Australia

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ATACAND® PLUS