

Consumer Medicine Information (CMI) summary

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

1. Why am I taking ADESAN?

ADESAN contains the active ingredient candesartan cilexetil. ADESAN is used to treat high blood pressure, also called hypertension. ADESAN is also used to treat heart failure in combination with other medicines to treat your condition. For more information, see Section [1. Why am I taking ADESAN?](#) in the full CMI.

2. What should I know before I take ADESAN?

Do not take if you have ever had an allergic reaction to ADESAN or any of the ingredients listed at the end of the CMI, have severe 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, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I take ADESAN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ADESAN 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 ADESAN?

- Your doctor will tell you the dose of ADESAN you should take. The usual dose is one 8 mg tablet or one 16 mg tablet taken daily. Sometimes an increase in dose to 32 mg once daily is needed.
- Swallow the tablets whole with a full glass of water. Do not crush or chew the tablets.

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

5. What should I know while taking ADESAN?

Things you should do	• Tell any doctor, dentist or pharmacist you visit that you are taking ADESAN. • If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. • If you are taking ADESAN for high blood pressure, drink plenty of water during exercise and hot weather, especially if you sweat a lot. If you do not drink enough water while taking ADESAN, you may faint or feel light-headed or sick. If you continue to feel unwell, tell your doctor. • If you are taking ADESAN for heart failure, restricted fluid intake is generally recommended. Speak with your doctor about how much water you should drink.
Things you should not do	• Do not stop taking your medicine or change the dosage unless you have discussed it with your doctor.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how ADESAN affects you. • You may feel dizzy or weary when you are taking ADESAN.
Looking after your medicine	• Store below 25°C. Protect from light. • Keep your tablets in the pack until it is time to take them.

For more information, see Section [5. What should I know while taking ADESAN?](#) 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: 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. 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.

Consumer Medicine Information (CMI)

This leaflet provides important information about taking ADESAN. **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 ADESAN.**

Where to find information in this leaflet:

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

1. Why am I taking ADESAN?

ADESAN contains the active ingredient candesartan cilexetil. ADESAN is a type of medicine called an angiotensin II receptor antagonist (or blocker).

ADESAN is used to treat high blood pressure (also called hypertension), and to treat heart failure. It is used in combination with other medicines to treat your condition.

Hypertension:

All people have blood pressure. This pressure helps to push blood all around your body. Your blood pressure changes during the day, depending on how busy you are or how you are feeling.

You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

Regular blood pressure checks are the only way of knowing that you have hypertension. There are usually no symptoms of hypertension, and you may feel fine. If hypertension is not treated, serious health problems such as stroke or heart attack and heart or kidney failure may occur.

ADESAN lowers blood pressure by dilating (expanding) small blood vessels from the heart, letting the blood be pumped around the body more easily.

Heart Failure:

Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as heart attack and does not mean that the heart stops working.

Heart failure may start off with no symptoms, but as the condition progresses, patients may feel short of breath or may get tired easily after light physical activity such as walking. Some patients may wake up short of breath at night. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet.

ADESAN helps to treat heart failure and may improve your symptoms.

One of the ways ADESAN helps heart failure is that it widens the blood vessels, so that the heart does not have to pump as hard to move the blood around the body. This also means that when you place extra demands on your heart, such as during exercise, the heart may cope better so you may not get short of breath as easily.

When used to treat heart failure, ADESAN is almost always used with other medicines called diuretics or fluid tablets. These medicines help the kidney get rid of excess fluid from the body.

Your doctor will have explained why you are being treated with ADESAN and told you what dose to take.

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

Your doctor may prescribe it for another reason.

ADESAN is not addictive.

2. What should I know before I take ADESAN?

Warnings

Do not take ADESAN if:

- you are allergic to:
 - any medicine containing candesartan cilexetil
 - any of the ingredients listed at the end of this leaflet
 - any medicine containing an angiotensin II receptor antagonist (or blocker).
- 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 take this medicine.

- **you have severe 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 (type I or II) or have kidney problems**
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should take this medicine, talk to your doctor.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes
- have any of the following medical conditions:
 - kidney problems
 - liver problems
 - heart problems
 - have experienced recent excessive vomiting or diarrhoea
 - a condition where your adrenal glands produce too much aldosterone, called primary hyperaldosteronism
- take any medicines for any other condition

You may have to take a lower dose of ADESAN if you have these conditions.

If you have not told your doctor about any of the above, tell him/her before you start taking ADESAN.

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 ADESAN if you are pregnant or planning to become pregnant.

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

Do not breast-feed if you are taking ADESAN.

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

Use in children

Do not give ADESAN to children.

There is no information about its use in children, so ADESAN is not recommended for 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 may interfere with ADESAN and affect how it works. 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 and angiotensin-converting-enzyme (ACE) inhibitors especially if you have diabetes-related kidney problems such as enalapril, lisinopril, ramipril and captopril
- mineralocorticoid receptor antagonists (MRAs), such as spironolactone and eplerenone, medicines used to treat heart failure
- heparin, a medicine used to stop blood from clotting
- trimethoprim/sulfamethoxazole, an antibiotic

You may need different amounts of your medicines, or you may need to take different medicines.

It may be necessary to have regular blood tests done if you take any of these 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 ADESAN.

4. How do I take ADESAN?

How much to take

- The usual dose is one 8 mg tablet or one 16 mg tablet taken daily. Sometimes an increase in dose to 32 mg once daily is needed. Your doctor will tell you the dose of ADESAN you should take.
- Follow the instructions provided and take ADESAN until your doctor tells you to stop.

When to take ADESAN

- Take ADESAN once a day, at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How to take ADESAN

- Swallow the tablets whole with a full glass of water.
- Do not crush or chew the tablets.
- It does not matter if you take ADESAN with food or on an empty stomach.

How long to take it

- Continue taking your medicine for as long as your doctor tells you to.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take ADESAN

ADESAN should be taken 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 your medicine as you would normally.

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 are not sure what to do, ask your doctor or pharmacist.

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

If you take too much ADESAN

If you think that you or anyone has taken too much ADESAN, urgent medical attention may be needed.

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.

Symptoms of an overdose may include headache and feel sick (nausea), dizzy and very tired.

5. What should I know while taking ADESAN?

Things you should do

- **Take ADESAN exactly as your doctor has told you.**
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 ADESAN.
- Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.
- If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.
It may affect other medicines used during surgery.
- **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 do 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 ADESAN.**
You should not take ADESAN if you are pregnant or thinking about becoming pregnant. Your doctor can discuss treatment options with you.

Things you should not do

- Do not take ADESAN 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 change the dosage unless you have discussed it with your doctor.

Things to be careful of

- **If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**
- **If you are taking ADESAN for high blood pressure, drink plenty of water during exercise and hot weather, especially if you sweat a lot.**
- **If you do not drink enough water while taking ADESAN, you may faint or feel light-headed or sick.**

This is because your body doesn't have enough fluid and your blood pressure is low. If you continue to feel unwell, tell your doctor.

- **If you are taking ADESAN for heart failure, restricted fluid intake is generally recommended. Speak with your doctor about how much water you should drink.**

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

Lifestyle measures that help reduce heart disease risk

By following these simple measures, you can further reduce the risk from heart disease:

- Quit smoking and avoid second-hand smoke.
- Limit alcohol intake.
- Enjoy healthy eating by:
 - eating plenty of vegetables and fruit;
 - reducing your saturated fat intake (eat less fatty meats, full fat dairy products, butter, coconut and palm oils, most take-away foods, commercially-baked products).
- Be active. Progress, over time, to at least 30 minutes of moderate intensity physical activity on 5 or more days each week. Can be accumulated in shorter bouts of 10 minutes duration. If you have been prescribed anti-angina medicine, carry it with you when you are being physically active.
- Maintain a healthy weight.
- Discuss your lifestyle and lifestyle plans with your doctor.
- For more information and tools to improve your heart health, call Heartline, the Heart Foundation's national telephone information service, on 1300 36 27 87 (local call cost).

Know warning signs of heart attack and what to do:

- Tightness, fullness, pressure, squeezing, heaviness or pain in your chest, neck, jaw, throat, shoulders, arms or back.

- You may also have difficulty breathing, or have a cold sweat or feel dizzy or light headed or feel like vomiting (or actually vomit).
- If you have heart attack warning signs that are severe, get worse or last for 10 minutes even if they are mild, call triple zero (000). Every minute counts.

Driving or using machines

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

ADESAN may cause dizziness or weariness in some people during treatment.

Looking after your medicine

- Store below 25°C. Protect from light.
- Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

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.

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.

Getting rid of any unwanted medicine

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

Do not take 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.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
General disorders: • headache • dizziness • weariness	Speak to your doctor if you have any of these less serious side effects and they worry you.
Infection related:	

Less serious side effects	What to do
• chest or throat infection • flu-like symptoms Stomach (gastrointestinal) related: • feeling sick (nausea, vomiting) Joint or muscle related: • back pain	

Serious side effects

Serious side effects	What to do
Joint or muscle related: • aching muscles, tenderness or weakness in the muscle	Tell your doctor as soon as possible if you notice any of these serious side effects.
Allergy related: • swelling of the face, lips, tongue or throat • swelling of the hands, feet or ankles • rash, itchiness or hives Lung related: • harsh sounds when breathing Liver related: • jaundice (yellowing of the skin and/or eyes) Blood related: • 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 • changes in your potassium, sodium and red or white blood cell levels may occur. Such changes are usually detected by a blood test • symptoms that may indicate high potassium levels in the blood include nausea, diarrhoea, muscle weakness and changes in heart rhythm Kidney related:	

Serious side effects	What to do
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)	

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 ADESAN contains

Active ingredient (main ingredient)	candesartan cilexetil (4, 8, 16 or 32 mg)
Other ingredients (inactive ingredients)	- lactose monohydrate - carmellose calcium - glyceryl monostearate - hypromellose - iron oxide red CI77491 (ADESAN 8 mg, 16 mg and 32 mg only) - maize starch - magnesium stearate
Potential allergens	sugars as lactose

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

What ADESAN looks like

- ADESAN 4 mg:** A white to off white round, biconvex tablet debossed with "M" on left side of the breakline and "C" on the right side of the breakline on one side of the tablet and "24" on the other side (AUST R 171019).
- ADESAN 8 mg:** A mottled pink, round, biconvex tablet debossed with "M" on left side of the breakline and "C" on right side of the breakline on one side of the tablet and "25" on the other side (AUST R 171022).

- ADESAN 16 mg:** A mottled pink, round, biconvex tablet debossed with "M" on left side of the breakline and "C" on right side of the breakline on one side of the tablet and "31" on the other side (AUST R 171016).
- ADESAN 32 mg:** A mottled pink, round, biconvex tablet debossed with "MC" above the breakline and "32" below the break line on one side of the tablet and plain on the other side (AUST R 171017).

All strengths are available in blister pack of 30 tablets.

Who distributes ADESAN

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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