

APO-Eplerenone tablets

Eplerenone

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 APO-Eplerenone?

APO-Eplerenone contains the active ingredient Eplerenone. APO-Eplerenone is used to treat heart failure in patients who have experienced heart attack.

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

2. What should I know before I use APO-Eplerenone?

Do not use it if you have ever had an allergic reaction to Eplerenone 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 APO-Eplerenone?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Eplerenone 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 APO-Eplerenone?

- Take your medicine at about the same time each day. Taking at the same time each day will have the best effect. It will also help you remember when to take it.
- Swallow the tablet whole with a full glass of water.

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

5. What should I know while using APO-Eplerenone?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are using APO-Eplerenone.• Tell your doctor if you have excess vomiting or diarrhoea while taking APO-Eplerenone
Things you should not do	<ul style="list-style-type: none">• Do not take this medicine 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.
Driving or using machines	<ul style="list-style-type: none">• This medicine may cause dizziness and feeling faint in some people.• If you do not drive, operate machinery or do anything else that could be dangerous.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.• Alcohol may have some effects with APO-Eplerenone.
Looking after your medicine	<ul style="list-style-type: none">• Keep the medicine in the pack until it is time to take them.• If you take the tablets out of the pack, they may not keep well

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

6. Are there any side effects?

The common side effects include feeling light headed, dizzy or faint, headache, stomach or bowel problems, feeling sick (nausea), vomiting, diarrhea, constipation, flatulence, cough, back pain.

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-Eplerenone tablets

Active ingredient(s): *Eplerenone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Eplerenone. **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 APO-Eplerenone.**

Where to find information in this leaflet:

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

1. Why am I using APO-Eplerenone?

APO-Eplerenone contains the active ingredient eplerenone. APO-Eplerenone belongs to a group of medicines called 'selective aldosterone, a substance made by your body. Aldosterone is important for regulating blood pressure and is one of the factors involved in heart function. Sometimes aldosterone can cause changes in our body that lead to heart failure. Eplerenone works by blocking the action of aldosterone and slowing the progression of heart failure by reducing heart damage.

APO-Eplerenone is used to

- Treat heart failure in patients who have experienced a heart attack.
- Reduce the risk of death or need for hospitalization due to heart failures in patients with chronic heart failure.

A heart attack occurs when one of the major blood vessels supplying blood to your heart becomes blocked.

This means that your heart cannot receive the oxygen it needs and becomes damaged.

This may lead to further problems, such as heart failure, irregular heart rhythms and blood clots.

Heart failure means that the heart muscle is weak and cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as heart attack, and may start off with mild or 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 or have to prop their heads-up during sleep to avoid this problem. Fluid may collect in

different parts of the body, often first noticed as swollen ankles and feet.

2. What should I know before I use APO-Eplerenone?

Warnings

Do not use APO-Eplerenone if:

- You are allergic to eplerenone, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- 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.

Check with your doctor if you:

- Have or had any other medical conditions
 - Very high levels of potassium in your blood
 - Severely reduced kidney function
 - Severe liver problems
- take any medicines for any other condition
 - potassium-sparing diuretics (e.g., spironolactone, amiloride), used to remove fluid from the body
 - ketoconazole and itraconazole, used to treat fungal infections
 - clarithromycin, used to treat bacterial infections
 - saquinavir and ritonavir, used to treat HIV infections

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor 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.

Before you start to take it

Tell your doctor if you have any allergies to any other medicines, foods, preservatives, or dyes.

Tell your doctor if you have or have had any of the following medical condition:

- high levels of potassium in your blood
- diabetes
- long term kidney disease
- liver problems

If you have not told your doctor about any of the above, tell them before you start taking these medicines.

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 eplerenone may interfere with each other. These include:

- Angiotensin converting enzymes (ACE)inhibitors and sartans (e.g., quinapril and losartan), used to treat high blood pressure.
- Non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., aspirin and ibuprofen), used to treat pain and inflammation.
- Lithium, a medicine used to treat mood swings.
- Neuroleptics and tricyclic anti-depressants, used to treat pain and inflammation.
- Lithium, a medicine used to treat mood swings.
- Neuroleptics and tricyclic antidepressants, used to treat certain medical illness.
- St John's Wort, used in the management of depression
- Carbamazepine, used to control seizures, facial pain, or certain types of mood disorders
- Phenytoin and phenobarbitone, medicines used to control seizures
- Potassium-sparing diuretics (e.g., spironolactone, amiloride)
- Potassium supplements, salt substitutes which contain potassium or salt tablets.
- Medicines used to treat fungal infections (e.g., ketoconazole, itraconazole, fluconazole)
- Certain antibiotics used to treat bacterial infections (e.g., erythromycin, trimethoprim, rifampicin)
- Saquinavir and ritonavir, medicines used to treat HIV infections
- Immunosuppressive agents (e.g., cyclosporin, tacrolimus)
- Baclofen, a muscle relaxant
- Prazosin, used to treat high blood pressure
- Alfuzosin, used to treat benign prostatic hyperplasia
- Amifostine, used to combination with cancer treatments
- Any other medicines used to treat high blood pressure or hear failure (e.g., verapamil)

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

Your doctor and pharmacists have more information or medicines to be careful with or avoid while taking this medicine.

Other medicines not listed above may interact with eplerenone.

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-Eplerenone.

4. How do I use APO-Eplerenone?

How much to take / use

- Your doctor will tell you how much of this medicine you should take. This may depend on your age, your kidney condition, the potassium level in your blood, and whether you are taking any other medicine.
- The usual starting dose is one 25mg tablet taken once a day. After about four weeks, your doctor may increase the dose to one 50mg tablet once a day.

When to take / use APO-Eplerenone

- APO-Eplerenone should be used at 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.
- It does not matter if this medicine is taken before or after food.

How to take APO-Eplerenone

Swallow the tablets whole with a full glass of water.

If you forget to use APO-Eplerenone

APO-Eplerenone should be used regularly at the same time each day. If it is less than 12 hours before 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 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.

This may increase the chance of you getting an unwanted side effect.

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 use too much APO-Eplerenone

If you think that you have used too much APO-Eplerenone, 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 APO-Eplerenone?

Things you should do

Call your doctor straight away if you:

Remind any doctor, dentist, or pharmacist you visit that you are using APO-Eplerenone.

- If you are about to start on any new medicine, remind your doctor and pharmacist that you are taking APO-Eplerenone.
- Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.
- If you become pregnant while taking this medicine, tell your doctor immediately.
- If you are going to have surgery, tell the surgeon or anesthetist that you are taking this medicine.
- If you are about to have any blood tests, tell your doctor that you are taking this medicine.
- Tell your doctor if you feel light-headed or dizzy after taking your first dose of this medicine, or when your dose is increased.
- 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 APO-Eplerenone, you may feel faint, light-headed, or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.

Tell your doctor if you have excess vomiting or diarrhea while taking eplerenone.

You may lose too much water and salt and your blood pressure may drop too much.

Tell your doctor if you are taking salt tablets can lead to serious side effects.

Keep all of your doctors' appointments so that your progress can be checked.

Your doctor may occasionally do a blood test to check your potassium levels and see how your kidneys are working. Your doctor may adjust your dose of this medicine depending on the potassium levels in your blood.

Things you should not do

- Do not take this medicine 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.

If you stop taking it suddenly, your condition may worsen, or you may have unwanted side effects.

Things to be careful of

Driving or using machines

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

APO-Eplerenone may cause dizziness and feeling faint in some people. If you have any of these symptoms, do not drive or operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy, or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may have some effects with APO-Eplerenone.

Looking after your medicine

- 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.
- Keep your medicine in a cool dry place where the temperature stays below 25°C.
- Do not store this medicine or any other medicine in the bathroom or near the sink.

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.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half-meters above the ground is a good place to store medicine.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking the medicine or the 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.

If you are over 65 years of age you may have an increased chance of having some side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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">Feeling light-headed, dizzy, or faint headacheStomach or bowel problems, feeling sick (nausea), vomiting, diarrhoea, constipation, flatulence.CoughBack pain	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">Rash, itchy skinSore throat, high temperature, signs of an infectionHeart flutters, increased heart rateUnusual tiredness, weakness, feeling weak and generally unwellMuscle spasms and pain, abdominal painEnlargement of the	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.

<ul style="list-style-type: none">breasts in menReduced sense of touchIncreased sweatingProblems with sleeping	
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Very serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">Shortness of breath, swelling of the feet or legs due to fluid build upChest pain which may spread to the neck and shouldersSwelling of the face, lips, mouth, tongue, or throat may cause difficulty in swallowing or breathing.	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 you may need urgent medical attention or hospitalization.

Other side effects not listed above may also occur in some people.

Some side effects (such as changes in potassium or cholesterol levels, thyroid function) can only be found when your doctor does blood tests to check your progress.

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 APO-Eplerenone contains

Active ingredient (Main ingredient)	Eplerenone
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Other ingredients (Inactive ingredients)	<ul style="list-style-type: none"> • Lactose monohydrate • Microcrystalline cellulose • Croscarmellose sodium • Hypromellose • Magnesium stearate • Purified talc • Titanium dioxide • Macrogol 6000 • Iron oxide yellow • Iron oxide red
Potential allergens	Contain lactose

This medicine does not contain sucrose, gluten, tartrazine, or any other azo dyes.

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

What APO-Eplerenone looks like

25mg tablet:

APO-Eplerenone is yellow, round, biconvex, film coated tablet, engraved with "E25" on one side. AUST R 295709.

Pack size of 30 tablets.

50mg tablet:

APO-Eplerenone is a yellow, round, biconvex, film coated tablet, engraved with "E50" on one side. AUST R 295708.

Pack size of 30 tablets.

Who distributes APO-Eplerenone

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

www.arrotex.com.au

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