

APO-Eplerenone tablets

Eplerenone

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about eplerenone. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

APO-Eplerenone tablets are used to:

- treat heart failure in patients who have experienced a heart attack.
- reduce the risk of death or need for hospitalisations due to heart failure 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.

How it works

Eplerenone belongs to a group of medicines called 'selective aldosterone blockers' that stop the action of 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.

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

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

There is not enough information to recommend the use of this medicine in children.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing eplerenone
- any of the ingredients listed at the end of this leaflet

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

Do not take this medicine if you have or have had any of the following medical conditions:

- very high levels of potassium in your blood
- severely reduced kidney function
- severe liver problems

Do not take eplerenone if you are currently taking any of the following medicines:

- 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

Do not take this medicine after the expiry date printed on the pack 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 start taking this medicine, talk to your doctor.

Before you start to take it

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

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

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

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and eplerenone may interfere with each other. These include:

- angiotensin converting enzyme (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 antidepressants, used to treat certain mental illnesses
- 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 in combination with cancer treatments
- any other medicines used to treat high blood pressure or heart 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 pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Other medicines not listed above may interact with eplerenone.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much of this medicine you should take. This may depend upon your age, your kidney condition, the potassium level in your blood, and whether or not you are taking any other medicines.

The usual starting dose is one 25 mg tablet taken once a day. After about four weeks, your doctor may increase the dose to one 50 mg tablet once a day.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine 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.

It does not matter if this medicine is taken before or after food.

How long to take it

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

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.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

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 as you would normally.

Do not take a double dose to make up for the dose that 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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of

this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much of this medicine, you may feel light-headed.

While you are taking this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking 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 anaesthetist 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 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 diarrhoea 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.

Taking this medicine together with salt tablets can lead to serious side effects.

Keep all of your doctor's 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 must 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

Be careful driving or operating machinery until you know how this medicine affects you.

This medicine may cause dizziness and feeling faint in some people. If you have any of these symptoms, do not drive, 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.

This medicine helps most people with heart failure, but it may have unwanted side effects in some people. All medicines can

have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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 lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- feeling light-headed, dizzy or faint, headache
- stomach or bowel problems, feeling sick (nausea), vomiting, diarrhoea, constipation, flatulence
- cough
- back pain

The above list includes the more common side effects of eplerenone.

Tell your doctor as soon as possible if you notice any of the following:

- rash, itchy skin
- sore throat, high temperature, signs of an infection

- heart flutters, increased heart rate
- unusual tiredness, weakness, feeling weak and generally unwell
- muscle spasms and pain, abdominal pain
- enlargement of the breasts in men
- reduced sense of touch
- increased sweating
- problems with sleeping

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- shortness of breath, swelling of the feet or legs due to fluid build up
- chest pain which may spread to the neck and shoulders
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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.

Storage and disposal

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 a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

25 mg tablet:

Yellow, round, biconvex film coated tablet, engraved with "E25" on one side. AUST R 295709.

Pack size of 30 tablets.

50 mg tablet:

Yellow, round, biconvex film coated tablet, engraved with "E50" on one side. AUST R 295708.

Pack size of 30 tablets

* Not all strengths may be available.

Ingredients

Each tablet contains 25 mg or 50 mg eplerenone as the active ingredient.

It also contains the following:

- lactose monohydrate
- microcrystalline cellulose
- croscarmellose sodium

- hypromellose
- magnesium stearate
- purified talc
- titanium dioxide
- macrogol 6000
- iron oxide yellow
- iron oxide red.

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

Sponsor

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