

EPLERENONE AN

Eplerenone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about EPLERENONE AN.

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 EPLERENONE AN against the benefits it is expected to 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 EPLERENONE AN is used for

What EPLERENONE AN does

- **This medicine is used to treat heart failure in patients who have experienced a heart attack.**

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.

- **This medicine is also used to reduce the risk of death or need for hospitalisations due to heart failure in patients with chronic heart failure.**

How EPLERENONE AN works

Your body makes a substance called aldosterone. It 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 AN works by blocking the action of aldosterone, and slowing the progression of heart failure by reducing heart damage.

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

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.

There is no evidence that this medicine is addictive.

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

Use in children

The safety and effectiveness of EPLERENONE AN in children have not been established.

Before you take EPLERENONE AN

When you must not take it

Do not take EPLERENONE AN if you have an allergy to:

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

Some of the symptoms of an allergic reaction may include:

- skin rash
- itchiness
- shortness of breath
- swelling of the face, lips or tongue
- muscle pain or tenderness
- joint pain.

Do not take EPLERENONE AN if you have or have had any of the following medical conditions:

- very high levels of potassium in your blood

- severely reduced kidney function. Your doctor will determine your kidney function.
- Severe liver problems.

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

- potassium-sparing diuretics (e.g. spironolactone, amiloride), used to help the kidneys get rid of salt and water by increasing the amount of urine produced
- ketoconazole and itraconazole used to treat fungal infections
- clarithromycin, used to treat bacterial infections
- saquinavir, ritonavir, for the treatment of HIV infections.

Taking EPLERENONE AN together with the above medicines can lead to serious side effects.

Do not take this medicine if you are pregnant.

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

Do not breast-feed if you are taking this medicine.

The active ingredient in EPLERENONE AN may pass into breast milk and there is a possibility that your baby may be affected.

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 breast-feeding.

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 EPLERENONE AN.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines you buy over the counter from a pharmacy or supermarket
- all complementary and alternative therapies
- anything you buy from a health food shop.

Some medicines may be affected by EPLERENONE AN 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 will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- medicines known as angiotensin converting enzyme (ACE) inhibitor and/or angiotensin receptor blocker (ARB), such as quinapril, losartan. These are used to treat high blood pressure and some other heart conditions and may increase the risk of high potassium levels in your blood.
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation including aspirin and ibuprofen.
- lithium, a medicine used to treat mood swings
- neuroleptics, used to treat certain mental illnesses
- 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, such as spironolactone, amiloride
- potassium supplements, or salt substitutes which contain potassium
- medicines used to treat fungal infections such as ketoconazole, itraconazole
- certain antibiotics used to treat bacterial infections, such as erythromycin, trimethoprim, rifampicin
- saquinavir, ritonavir, for the treatment of HIV infections
- immunosuppressive agents such as cyclosporin, tacrolimus
- baclofen, a muscle relaxant
- prazosin, used to treat high blood pressure and other medical conditions
- alfuzosin, for the treatment of benign prostatic hyperplasia
- amifostine, used in combination with cancer treatments
- any other medicines used to treat high blood pressure or heart failure.

If you are not sure if you are taking any of these medicines mentioned in this leaflet, check with your doctor or pharmacist.

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

Tell your doctor if you are taking salt tablets.

Taking EPLERENONE AN together with salt tablets can lead to serious side effects.

How to take EPLERENONE AN

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 many tablets you need to take each day. 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 of EPLERENONE AN is 25 mg taken once a day. After about 4 weeks, your doctor may increase the dose to 50 mg once a day.

Your doctor will do blood tests to help determine the correct dose of EPLERENONE AN for you.

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 the tablets.

Your tablets may be taken with or after a meal, or on an empty stomach.

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.

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 Australian Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much EPLERENONE AN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much EPLERENONE AN, you may feel light-headed.

While you are taking EPLERENONE AN

Things you must do

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 dose of EPLERENONE AN may be adjusted by your doctor, depending on the potassium levels in your blood.

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor that you are taking this medicine.

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 AN, 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.

If you have excess vomiting or diarrhoea while taking EPLERENONE AN, tell your doctor.

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

If you feel light-headed or dizzy after taking your first dose of EPLERENONE AN, or when your dose is increased, tell your doctor immediately.

Things you must not do

Do not take EPLERENONE AN 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 EPLERENONE AN affects you.

This medicine may cause dizziness and feeling faint in some people. If you have this symptom, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking EPLERENONE AN or your condition changes. Tell your doctor even if you think the problem is not connected with the medicine or is not listed in this leaflet.

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.

It is often difficult to tell whether side effects are the result of taking EPLERENONE AN, or the effects of your heart failure or side effects of other medicines you may be taking. For this reason it is important to report any change in your condition. Your doctor may want to change your dose or advise you to stop taking EPLERENONE AN.

If you are over 65 years of age you may have an increased chance of having some side effects, as you may be more sensitive to the effects of the medication.

Do not be alarmed by the following list 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 if...

The following list includes the more common or noticeable side effects of your medicine.

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

- feeling light-headed, dizzy or faint
- stomach or bowel problems
 - feeling sick (nausea) or vomiting
 - diarrhoea
 - constipation
 - flatulence or wind
- cough
- sore throat
- headache
- rash, itchy skin
- high temperature, signs of an infection
- back pain.

Tell your doctor as soon as possible if...

The following list includes side effects that may require medical attention. Serious side effects are rare.

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

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

Go to hospital if...

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- 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.

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 patients.

Some of these side effects (for example, changes in potassium levels, thyroid function, or cholesterol level) can only be found when your doctor does tests from time to time to check your progress.

After taking EPLERENONE AN

Storage

Keep your EPLERENONE AN tablets in the pack until it is time to take them.

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

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store EPLERENONE AN 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

Packs contain 20, 30, 60, 90, and 120 tablets.

25 mg tablet

Beige, round, biconvex tablets, debossed "25" on one side.

50 mg tablet

Beige, round, biconvex tablets, debossed "50" on one side.

Ingredients

The active ingredient in EPLERENONE AN is eplerenone.

- EPLERENONE AN 25 tablet contains 25 mg eplerenone
- EPLERENONE AN 50 tablet contains 50 mg eplerenone.

EPLERENONE AN tablets also contain:

- lactose
- microcrystalline cellulose
- croscarmellose sodium
- hypromellose
- sodium lauryl sulfate
- purified talc
- magnesium stearate
- titanium dioxide
- macrogol 400
- polysorbate 80
- iron oxide yellow
- iron oxide red.

This medicine does not contain sucrose, gluten, or tartrazine.

Sponsor:

Generic Partners Pty Ltd
Level 1 313 Burwood Road
HAWTHORN VIC 3122
Australia.

Name and address of the distributor

Amneal Pharma Australia Pty Ltd
South Yarra VIC 3141 Australia

Australian registration numbers

25 mg AUST R 231448

50 mg AUST R 231455

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