Package leaflet: Information for the user

Eplerenone 25 mg and 50 mg film-coated

tablets
eplerenone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Eplerenone tablets are and what it is used for
2. What you need to know before you take Eplerenone tablets
3. How to take Eplerenone tablets
4. Possible side effects
5. How to store Eplerenone tablets
6. Contents of the pack and other information

1. What Eplerenone tablets are and what it is used for

Eplerenone tablets contains the active substance eplerenone. Eplerenone belongs to a group of medicines known as selective aldosterone blocking agents. These blocking agents inhibit the action of aldosterone, a substance produced within the body, which controls your blood pressure and heart function. High levels of aldosterone can cause changes in your body that lead to heart failure.

Eplerenone is used to treat your heart failure to prevent worsening and reduce hospitalisations if you have:
1. had a recent heart attack, in combination with other drugs that are used to treat your heart failure, or
2. have persistent, mild symptoms despite the treatment you have been receiving so far.

2. What you need to know before you take Eplerenone tablets

Do not take Eplerenone tablets
- if you are **allergic to eplerenone or any of the other ingredients** of this medicine (listed in section 6).
- if you have **high levels of potassium** in your blood (hyperkalaemia).
- if you are taking **groups of drugs which help you to excrete excessive body fluid** (potassium sparing diuretics).
- if you have **severe kidney disease**.
- if you have **severe liver disease**.
- if you are **taking medicines** that are used **to treat fungal infection** (ketoconazole or itraconazole).
- if you are taking **antiviral medication for treating HIV** (nelfinavir or

ritonavir).
- if you are **taking antibiotics** used to treat bacterial infections (clarithromycin or telithromycin).
- if you are **taking nefazodone** used to treat depression.
- if you are taking medicines used to treat certain **heart conditions or hypertension** (so called angiotensin converting enzyme (ACE) inhibitor and an angiotensin receptor blocker (ARB)) together.

Warnings and precautions
Talk to your doctor or pharmacist or nurse before taking Eplerenone tablets
- if you have **kidney or liver disease** (see also "Do not take Eplerenone tablets").
- if you are **taking lithium** (usually given for manic depressive disorder, also called bipolar disorder).
- if you are **taking tacrolimus or cyclosporin** (used to treat skin conditions such as psoriasis or eczema, and to prevent rejection after organ transplantation).

Children and adolescents
The safety and efficacy of eplerenone in children and adolescents have not been established.

Other medicines and Eplerenone tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- **Itraconazole or ketoconazole** (used to treat fungal infections), **ritonavir**, **nelfinavir** (antiviral medication for treating HIV), **clarithromycin**, **telithromycin** (used to treat bacterial infections) or **nefazodone** (used to treat depression) as these drugs reduce the break-down of eplerenone, thereby prolonging its effect on the body.
- **Potassium sparing diuretics** (drugs which help you to excrete excess body fluid) and **potassium supplements** (salt tablets) as these drugs increase the risk of high potassium levels in your blood.
- **Angiotensin converting enzyme (ACE) inhibitors** and **angiotensin receptor blockers (ARB) together** (which are used to treat high blood pressure, heart disease or particular kidney conditions) as these drugs may increase the risk of high potassium levels in your blood.

- **Lithium** (usually given for manic depressive disorder, also called bipolar disorder). Use of lithium together with diuretics and ACE inhibitors (used to treat high blood pressure and heart disease) has been shown to cause levels of lithium in the blood to become too high, which may cause side effects of: loss of appetite; visual impairment; tiredness; muscle weakness; muscle twitches.
- **Cyclosporin** or **tacrolimus** (used to treat skin conditions such as psoriasis or eczema, and to prevent rejection after organ transplantation). These drugs can cause kidney problems and therefore increase the risk of high potassium levels in your blood.
- **Non-steroidal anti-inflammatory drugs** (NSAIDs - certain pain killers such as ibuprofen, used to relieve pain, stiffness and inflammation). These drugs may lead to kidney problems and therefore increase the risk of high potassium levels in your blood.
- **Trimethoprim** (used to treat bacterial infections) may increase the risk of high potassium levels in your blood.
- **Alpha I blockers** (such as prazosin or alfuzosin) (used to treat high blood

pressure and particular prostate conditions) may lead to a fall in blood pressure and dizziness upon standing.
- **Tricyclic antidepressants** (such as amitryptyline or amoxapine) (for treatment of depressions), **antipsychotics** (also known as **neuroleptics**) (such as chlorpromazine or haloperidol) (for the treatment of psychiatric disorders), **amifostine** (used during cancer chemotherapy) and **baclofen** (used to treat muscle spasm). These drugs may lead to a fall in blood pressure and dizziness upon standing.
- **Glucocorticoids** (such as hydrocortisone or prednisone) (used to treat inflammation and certain skin conditions) and **tetracosactide** (mainly used for diagnosing and treating disorders of the adrenal cortex) may reduce the blood-pressure lowering effect of eplerenone.
- **Digoxin** (used in the treatment of heart conditions). Digoxin blood levels may be increased when taken together with eplerenone.
- **Warfarin** (an anti-clotting drug): Caution is warranted when taking warfarin because high levels of warfarin in the blood may cause changes in the effect of eplerenone on the body.
- **Erythromycin** (used to treat bacterial infections), **saquinavir** (antiviral medication for treating HIV), **fluconazole** (used to treat fungal infections), **amiodarone**, **diltiazem** and **verapamil** (for the treatment of heart problems and high blood pressure) reduce the break-down of eplerenone thereby prolonging the effect of eplerenone on the body.
- **St John's Wort** (herbal medicinal product), **rifampicin** (used to treat bacterial infections), **carbamazepine**, **phenytoin**, and **phenobarbital** (used, among others, to treat epilepsy) may increase the break-down of eplerenone and thus decrease its effect.

Eplerenone tablets with food and drink
Eplerenone may be taken with or without food.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The effect of eplerenone has not been evaluated during pregnancy in humans. It is not known if eplerenone is excreted in human breast milk. A decision should be made with your doctor, whether to discontinue breast-feeding or to discontinue the drug.

Driving and using machines
You may feel dizzy after taking eplerenone. If this should happen, do not drive or operate machinery.

Eplerenone tablets contain lactose
Eplerenone contains lactose (a type of sugar). If you have been told by your doctor that you have **an intolerance to some sugars**, contact your doctor before taking this medicinal product.

Eplerenone tablets contain sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Eplerenone tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Eplerenone tablets may be taken together with food or on an empty stomach. Swallow the tablets whole with plenty of water.

Eplerenone is usually administered together with other medication for heart failure e.g. beta blockers. The usual **starting dose is one 25 mg tablet once daily**, **increasing** after about 4 weeks **to 50 mg once daily** (either as one 50 mg tablet or two 25 mg tablets). The maximum dose regimen is 50 mg daily.

Blood potassium levels should be measured before starting eplerenone therapy, within the first week and at one month after the start of treatment or after a change in dose. The dose may be adjusted by your doctor, depending on the potassium levels in your blood.

Renal and hepatic impairment
If you have mild kidney disease, you should start on one 25 mg tablet every day. And if you have moderate kidney disease, you should start on one 25 mg tablet every other day. These doses may be adjusted if your doctor recommends and according to your blood potassium levels.
In patients with severe kidney disease, eplerenone is not recommended.

In patients with mild-to-moderate liver disease no adjustment of the starting dose is required. If you have liver or kidney problems, you may need more frequent testing of your blood potassium levels (see also "Do not take Eplerenone tablets").

Elderly
No adjustment of the starting dose is required.

Use in children and adolescents
Eplerenone is not recommended.

If you take more Eplerenone tablets than you should
If you take more eplerenone than you should, tell your doctor or pharmacist immediately. If you have taken too much of your medicine, the most likely symptoms will be low blood pressure (expressed as a light feeling in your head, dizziness, blurred vision, weakness, acute loss of consciousness) or hyperkalemia, high levels of potassium in the blood (expressed by muscle cramps, diarrhoea, nausea, dizziness or headache).

If you forget to take Eplerenone tablets
If it is almost time for your next tablet, skip the tablet you missed and take your next tablet when it is due.
Otherwise take the tablet as soon as you remember, providing there is more than 12 hours to when you are due to take your next tablet. Then go back to taking your medicine as you would normally.
Do not take a double dose to make up for the forgotten tablet.

If you stop taking Eplerenone tablets
It is important to keep taking eplerenone as prescribed unless your doctor tells you to stop your treatment.

If you have any further questions on the use of this medicine, ask your doctor

or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following:
You should seek immediate medical attention
• swollen face, tongue or throat
• difficulty swallowing
• hives and difficulties breathing
These are the symptoms of angioneurotic oedema, an uncommon (affecting up to 1 in 100 people) side effect.

Other reported side effects include:
Common side effects (may affect up to 1 in 10 people)
• Elevated potassium level in your blood (symptoms include muscle cramps, diarrhoea, nausea, dizziness or headache)
• fainting
• dizziness
• elevated quantity of cholesterol in your blood
• insomnia (difficulty sleeping)
• headache
• heart complaints e.g., irregular heartbeat and heart failure
• cough
• constipation
• low blood pressure
• diarrhoea
• nausea
• vomiting
• abnormal functioning of your kidney
• rash
• itching
• back pain
• feeling weak
• muscle spasm
• increased urea level in the blood
• increased creatinine blood levels which may indicate kidney problems

Uncommon side effects (may affect up to 1 in 100 people)
• Infection
• eosinophilia (increase in certain white blood cells)
• dehydration, elevated quantity of triglycerides (fats) in your blood
• low sodium blood levels
• fast heart beat
• inflammation of the gall bladder
• decreased blood pressure that can cause dizziness upon standing
• thrombosis (blood clot) in the leg
• sore throat
• flatulence
• underactive thyroid
• increase in blood glucose
• reduced sense of touch
• increased sweating

• musculoskeletal pain
• feeling generally unwell
• kidney inflammation
• enlargement of breasts in men
• changes in some blood test results

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Eplerenone tablets

Keep this medicine out of the sight and reach of children.
This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the blister and carton after 'EXP'. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Eplerenone tablets contain
- The active substance is eplerenone. Each tablet contains 25 mg or 50 mg eplerenone.
- The other ingredients are lactose monohydrate, cellulose microcrystalline (E460), croscarmellose sodium (E468), hypromellose (E464), sodium laurilsulfate, talc (E553b), magnesium stearate (tablet core); hypromellose (E464), polysorbate 80 (E433), macrogol 400, titanium dioxide (E171), iron oxide yellow (E172) (tablet coating).

What Eplerenone tablets look like and contents of the pack
Eplerenone 25 mg is a light yellow, round, biconvex film-coated tablet, debossed with 'E9RN' on one side and '25' on the other side.

Eplerenone 50 mg is a light yellow, round, biconvex film-coated tablet, debossed with 'E9RN' on one side and '50' on the other side.

Eplerenone tablets are available in blister packs of 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98 or 100 tablets; unit dose of 10x 1, 14 x 1, 20 x 1, 28 x 1, 30 x 1, 50 x 1, 56 x 1, 60 x 1, 84 x 1, 90 x 1, 98 x 1 or 100 x 1 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Consilient Health Limited
Floor 3, Block 3, Miesian Plaza
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