

3. How to take Eplerenone

Always take this medicine exactly as your doctor 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.

Patients with kidney or liver disease

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").

Elderly

No adjustment of the starting dose is required.

Use in children and adolescents

Eplerenone is not recommended for children and adolescents.

If you take more eplerenone 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

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 a forgotten tablet.

If you stop taking eplerenone

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)
- Dizziness
- Fainting
- 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 creatine 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 heartbeat
- 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 or pharmacist. 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

Keep this medicine out of the sight and reach of children.

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

This medicinal product does not require any special storage conditions.

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 contains

The active substance is eplerenone. Each tablet contains 25 mg or 50 mg eplerenone.

The other ingredients are lactose monohydrate, cellulose microcrystalline, croscarmellose sodium, hypromellose, sodium laurilsulfate and magnesium stearate.

The coating contains hypromellose, titanium dioxide, macrogol, polysorbate 80 and iron oxide yellow.

What eplerenone looks like and contents of the pack

The eplerenone 25 mg tablet is a yellow, round, biconvex film-coated tablet with a diameter approximately 6 mm and thickness approximately 3.0 mm.

The eplerenone 50 mg tablet is a yellow, round, biconvex film-coated tablet with a diameter approximately 7.5 mm and thickness approximately 3.7 mm.

Eplerenone 25 mg and 50 mg film-coated tablets are available in blister packs containing 10, 20, 28, 30, 50, 90, 100 or 200 tablets, in perforated unit dose blisters containing 10x1, 20x1, 28x1, 30x1, 50x1, 90x1, 100x1 or 200x1 tablets and bottles containing 10, 20, 28, 30, 50, 90, 100 or 200 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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