TBC

Package leaflet: Information for the patient

Eplerenone Mylan 25 mg film-coated tablets Eplerenone Mylan 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 Mylan is and what it is used for
2. What you need to know before you take Eplerenone Mylan
3. How to take Eplerenone Mylan
4. Possible side effects
5. How to store Eplerenone Mylan
6. Contents of the pack and other information

1. What Eplerenone Mylan is and what it is used for

Eplerenone Mylan 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 Mylan 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 Mylan

Do not take Eplerenone Mylan:
- 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 (hyperkalemia)
- if you are taking groups of drugs which help you to excrete excessive body fluid, (potassium sparing diuretics) or "salt tablets" (potassium supplements)
- 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 before taking Eplerenone Mylan
- if you have kidney or liver disease (see also "Do not take Eplerenone Mylan")
- if you are taking lithium (usually given for manic depressive disorder, also called bipolar disorder)
- if you are taking tacrolimus or ciclosporin (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 Mylan
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

You must not take Eplerenone with the following medications (see section "Do not take Eplerenone Mylan"):
- 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.

Please inform your doctor if you are taking any of the following medicines:
- 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.
- Ciclosporin 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 Mylan.
- Digoxin (used in the treatment of heart conditions). Digoxin blood levels may be increased when taken together with Eplerenone Mylan.
- 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 Mylan 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 Mylan thereby prolonging the effect of Eplerenone Mylan on the body (see section 3 'How to take Eplerenone Mylan').
- 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 Mylan and thus decrease its effect.

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 Mylan 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 Mylan. If this should happen, do not drive or operate machinery.

Eplerenone Mylan Tablets contain lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Eplerenone Mylan

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 Mylan is usually administered together with other medication for heart failure e.g. beta blockers. The recommended 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.

Mylan

Description	Eplerenone 25/50 mg All			Date: 28 APR 2015	Time: 11:52
Component Type	Leaflet	Pharma Code	TBC	No. of colours: 1	Page Count: 1/2
Affiliate Item Code	626512	SAP No.	N/A	Colours: Black	
Superceded Affiliate Item Code	349889	Vendor Job No.	253148	Non-Print Colours	
TrackWise PR No.	626512	Proof No.	1	Equate CMYK with	
MA No.	N/A	Client Market	Ireland	Main Font: Times	Body Text Size: 10 pt
Packing Site/Printer	Unichem Labs	Keyline/Drawing No.	N/A	Dimensions: 170 x 600mm	Min Text Size used: 10 pt
Supplier Code	N/A	Barcode Info	N/A		
Sign-offs					

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Blood potassium levels should be measured before starting Eplerenone Mylan 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.

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 Mylan 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 Mylan").

If you take some other medicines, your doctor may recommend you take a lower dose.

For the elderly: no adjustment of the starting dose is required.

For children and adolescents: Eplerenone Mylan is not recommended.

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

If you take more Eplerenone Mylan than you should
If you take more Eplerenone Mylan 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 Mylan
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 Mylan
It is important to keep taking Eplerenone Mylan 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:**

Common side-effects (may affect up to 1 in 10 people):
- heart attack
- abnormal functioning of your kidney – you may notice little or no urine being passed, or have lower back pain.

Uncommon side-effects (may affect up to 1 in 100 people):
- heart complaints e.g. irregular heart beat and heart failure
- inflammation of the gall bladder – you may have sudden sharp pain in the stomach that may spread towards the shoulders
- thrombosis (blood clot) in the leg
- kidney inflammation – you may notice lower back pain, cloudy urine or blood in the urine.

Not known (frequency cannot be estimated from the available data):
- swollen face, tongue or throat
- difficulty swallowing
- hives and difficulties breathing

These are the symptoms of angioneurotic oedema.

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
- infection
- cough
- constipation
- low blood pressure
- diarrhoea
- nausea
- rash
- itching
- muscle spasm and pain
- increased urea level in the blood

Uncommon side-effects (may affect up to 1 in 100 people):
- eosinophilia (increase in certain white blood cells)
- dehydration
- elevated quantity of cholesterol or triglycerides (fats) in your blood
- low sodium blood levels
- insomnia (difficulty sleeping)
- headache
- fast heart beat
- decreased blood pressure that can cause dizziness upon standing
- sore throat
- flatulence
- vomiting
- underactive thyroid
- increase in blood glucose
- reduced sense of touch
- increased sweating
- back pain
- feeling weak and generally unwell
- increased creatinine blood levels which may indicate kidney problems
- 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Eplerenone Mylan

Keep this medicine out of the sight and reach of children.
This medicine does not require any special storage conditions.
Do not use this medicine after the expiry date which is stated on the carton, bottle or blister 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 Mylan contains

- The active substance is eplerenone. Each film-coated tablet contains 25 mg or 50 mg eplerenone.
- The other ingredient are:

  Tablet Core
  Lactose monohydrate (see section 2, "Eplerenone Mylan Tablets contain lactose"), microcrystalline cellulose, croscarmellose sodium, hypromellose, sodiumlaurilsulfate, talc, magnesium stearate

  Film Coating
  Hypromellose, titanium dioxide (E171), macrogol, yellow iron oxide (E172), red iron oxide (E172), polysorbate

What Eplerenone Mylan looks like and contents of the pack
Eplerenone Mylan 25 mg film-coated tablets are yellow, film-coated, round, biconvex tablets, marked with 'EP1' on one side and 'M' on other side.

Eplerenone Mylan 50 mg film-coated tablets are yellow, film-coated, round, biconvex tablets, marked with 'EP2' on one side and 'M' on other side.

Eplerenone Mylan tablets are available in blister packs containing 20, 28, 30, 50, 90 and 100 tablets and single-unit dose blisters in packs containing 30 x 1, 50 x 1 and 90 x 1 tablets, or plastic bottles containing 28, 30, 90 and 250 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Manufacturer
McDermott Laboratories t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Mylan Hungary Kft., H-2900, Komarom, Hungary

Generics [UK] Limited, Station Close, Potters Bar, Hertfordshire, United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium:	Eplerenone Mylan 25 mg & 50 mg filmomhulde tabletten
Cyprus:	Eplerenone Mylan 25 mg & 50 mg Film-coated tablets
France:	Eplerenone Mylan 25 mg & 50 mg, comprimé pelliculé
Germany:	Eplerenon Mylan 25 mg & 50 mg Filmtabletten
Hungary:	Eplerenone Mylan 25 mg & 50 mg filmtabletta
Ireland:	Eplerenone Mylan 25 mg & 50 mg Film-coated Tablets
Italy:	Eplerenone Mylan
Luxembourg:	Eplerenone Mylan 25 mg & 50 mg comprimés pelliculés
Netherlands:	Eplerenon Mylan 25 mg & 50 mg, filmomhulde tabletten
Norway:	Eplerenone Mylan 25 mg & 50 mg tablett, filmdrasjert
Slovak Republic:	Eplerenon Mylan 25 mg & 50 mg, filmom obalené tablety
Spain:	Eplerenona Mylan 25 mg & 50 mg comprimidos recubiertos con pelicula EFG
United Kingdom:	Eplerenone 25 mg & 50 mg Film-coated tablets

This leaflet was last revised in 04/2015

Mylan

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Mylan		Date: 28 APR 2015	Time: 11:52
Description	Eplerenone 25/50 mg All	No. of colours: 1	Page Count: 2/2
Component Type	Leaflet	Pharma Code: TBC	Colours: Black
Affiliate Item Code	626512	SAP No.: N/A	Non-Print Colours:
Superceded Affiliate Item Code	349889	Vendor Job No.: 253148	Equate CMYK with:
TrackWise PR No.	626512	Proof No.: 1	Main Font: Times; Body Text Size: 10 pt
MA No.	N/A	Client Market: Ireland	Dimensions: 170 x 600mm; Min Text Size used: 10 pt
Packing Site/Printer	Unichem Labs	Keyline/Drawing No.: N/A	
Supplier Code	N/A	Barcode Info: N/A	
Sign-offs			