Package leaflet: Information for the patient

Spironolactone 12.5 mg Film-coated Tablets

Spironolactone 25 mg Film-coated Tablets

Spironolactone 50 mg Film-coated Tablets

Spironolactone 100 mg Film-coated Tablets

(spironolactone)

Your medicine is called spironolactone 12.5, 25, 50, 100 mg film-coated tablets, but it will be referred to as spironolactone tablets throughout this leaflet.

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 spironolactone tablets are and what they are used for

The active ingredient of the tablets is spironolactone. Spironolactone belongs to a group of medicines called ‘diuretics’ – you may know these as ‘water’ tablets.

You may have gone to your doctor because you had swollen ankles or were short of breath. This can happen when your heart's pumping action has become weak because of too much fluid in your body. This is called “congestive heart failure”. Pushing extra fluid around your body means your heart has to work harder. Your doctor has given you to help you lose the extra fluid from your body. This will mean your heart has to do less work. You lose the extra fluid as urine, so you may need to go to the toilet more often while you are taking spironolactone.

You can take spironolactone for the following illnesses:

- “Nephrotic syndrome” - a kidney disorder that causes too much fluid in your body
- “Ascites” - too much fluid in your abdomen and “oedema” - accumulation of fluid beneath skin or in one or more cavities of the body that produces swelling, for example caused by cirrhosis of the liver
- “Malignant ascites” - fluid containing cancer cells that collect in the abdomen
- “Primary aldosteronism” - extra fluid in your body caused by too much of a hormone called “aldosterone”.

Children should only be treated under guidance of a paediatric specialist.

If you have these illnesses, spironolactone tablets will help your body to get rid of the extra fluid.

You must talk to a doctor if you do not feel better or if you feel worse.

Children should only be treated under guidance of a paediatric specialist.

2. What you need to know before you take Spironolactone Tablets

Do not take Spironolactone Tablets

- if you are allergic to spironolactone or any of the other ingredients of this medicine (listed in section 6)
- if you cannot pass urine
- if you have severe kidney disease
- if you have Addison's disease; (a hormone deficiency characterised by extreme weakness, loss of weight and low blood pressure)
- if you have hyperkalaemia (raised blood potassium levels)
- if you are breast-feeding
- if you are taking water tablets (potassium sparing diuretics) or any potassium supplements
- if you are taking eplerenone (a medicine for high blood pressure)

Children with moderate to severe kidney disease must not take spironolactone.

Warnings and precautions

Talk to your doctor or pharmacist before taking Spironolactone tablets

- if you suffer from kidney disease especially children with hypertension or liver disease.
- if you are elderly. Your doctor will routinely assess you
- if you have difficulty passing urine
- if you have a disease that can result in electrolyte balance disturbance in your blood such as potassium or sodium
- if you have severe heart failure
- if you are pregnant

If you experience reduced kidney function or kidney failure you may have severe increases in the levels of potassium in your blood. This can affect the way your heart functions and in extreme cases this can be fatal.

Concomitant administration of spironolactone with certain medicines, potassium supplements and food rich in potassium may lead to severe hyperkalaemia (increased potassium blood level). The symptoms of severe hyperkalaemia might include muscle cramps, irregular heart rhythm, diarrhoea, nausea, dizziness or headache.

Other medicines and spironolactone tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, your doctor may wish to alter your dose of spironolactone tablets if you are taking any of the following:

- digoxin or carbenoxolone
- medicines for high blood pressure including angiotensin-converting enzyme (ACE) inhibitors
- other diuretics
- non-steroidal anti-inflammatory drugs (NSAID) such as aspirin, indomethacin, mefenamic acid or ibuprofen
- potassium supplements
- heparin or low molecular weight heparin (medicines used to prevent blood clots)

- antipyrine
- medicines known to cause hyperkalaemia (raised blood potassium levels)
- trimethoprim and trimethoprim-sulfamethoxazole

Tell your doctor, if you are using abiraterone for treatment of prostate cancer

Spironolactone reduces your responsiveness to noradrenaline. If you are going to have an operation where you will be given an anaesthetic, tell the doctor in charge that you are taking spironolactone.

Spironolactone tablets with food, drink and alcohol

See section 3 "How to take spironolactone tablets"

Pregnancy, breast-feeding and fertility

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.

Spironolactone tablets should not be used if you are breast-feeding. You should discuss the use of spironolactone with your doctor, who will advise you to consider an alternative method of feeding your baby while you are taking this medicine.

Driving and using machines

Take care if you drive or operate machinery. Drowsiness and dizziness have been associated with spironolactone tablets treatment and this may affect your ability to drive or operate machinery safely.

Spironolactone tablets contain lactose

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take spironolactone 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.

The pharmacist's label on the pack also gives this information. The number of tablets you need to take depends on your illness.

Recommended dose

This medicine should be taken once a day with food.

Adults

The adult dose varies from 25mg to 400mg spironolactone a day, depending on the condition being treated. If you are not sure how much to take, ask your doctor or pharmacist.

Elderly

Your doctor will start you on a low starting dose and gradually increase the dosage as needed to obtain the desired effect.

Use in children and adolescents

If you are giving spironolactone tablets to a child, the number of tablets you give will depend on the child's weight. Your doctor will work out the number of tablets that you should give.

If you take more spironolactone tablets than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital accident and emergency department immediately. The symptoms of an overdose are feeling drowsy, dizzy, feeling dehydrated and

you may feel confused. You may also feel or be sick, suffer from diarrhoea and may have skin rashes that will appear as flat red areas of skin with overlapping small raised bumps.

Changes in your blood sodium and potassium levels may leave you feeling weak and suffering from tingling, prickling or numbness of the skin and/or muscle spasms but these symptoms are unlikely to be associated with severe overdosage.

If you forget to take spironolactone tablets

If you forget to take your tablet, take it as soon as you remember, unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking spironolactone tablets

It is important to keep taking spironolactone tablets until your doctor tells you to stop, even if you start to feel better.

If you stop taking the tablets too soon, your condition may get worse.

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.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, the symptoms can be severe.

Itchiness and blistering of the skin around the lips and the rest of the body (Stevens-Johnson syndrome)

Detachment of the top layer of skin from the lower layers of skin, all over the body (toxic epidermal necrolysis)

Skin rash, fever and swelling (which could be symptoms of something more serious, drug rash and eosinophilia and systemic symptoms)

Yellow skin and eyes (jaundice), spironolactone tablets can cause impairment of liver function

Irregular heartbeat which can be fatal, tingling sensation, paralysis (loss of muscle function) or difficulty in breathing; which may be symptoms of raised potassium levels in your blood. Your doctor will conduct regular blood tests to monitor potassium and other electrolyte levels. They may stop your treatment if necessary.

Other side effects of spironolactone tablets by frequency:

Very common: may affect more than 1 in 10 people

- raised potassium in the blood (hyperkalaemia)

Common: may affect up to 1 in 10 people

- confusion, dizziness
- nausea
- muscle or leg cramps
- sudden kidney failure
- excessive growth of breast tissue in men (gynaecomastia, this goes away when treatment is stopped), breast lumps, breast pain
- general weakness
- skin rash, generalised itchiness

Uncommon: may affect up to 1 in 100 people

- disturbances in body electrolytes
- abnormal liver function
- skin allergy with development of itchiness and weals (urticaria)
- menstrual problems in women, breast pain

Not known: frequency cannot be estimated from the available data

- stomach upset
- change in sex drive for both men and women (libido)
- reduced number of cells that fight infection - white cells (leukopenia), reduced number of cells that help with clotting (thrombocytopenia)
- excessive hair growth (hypertrichosis), skin condition presenting with fluid - filled blisters (pemphigoid)
- hair loss

Reporting side-effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effect not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: 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 spironolactone tablets

- Keep out of sight and reach of children.
- This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light.
- Do not use this medicine after the expiry date which is stated on the carton or blister label 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 spironolactone tablets contain:

The active substance is spironolactone. Each spironolactone 12.5 mg film-coated tablet contains 12.5 mg of spironolactone. Each spironolactone 25 mg film-coated tablet contains 25 mg of spironolactone. Each spironolactone 50 mg film-coated tablet contains 50 mg of spironolactone. Each spironolactone 100 mg film-coated tablet contains 100 mg of spironolactone.

The other ingredients are lactose monohydrate, calcium sulphate dihydrate, crospovidone, povidone, maize starch, magnesium stearate, hypromellose, titanium dioxide, polyethylene glycol.

What spironolactone tablets look like and contents of the pack

Spironolactone 12.5 mg film-coated tablets are white to off-white, round, biconvex tablets debossed on one side with "S1", approximately 5.75 mm in diameter

Spironolactone 25 mg film-coated tablets are white to off-white, round, biconvex tablets debossed on one side with "S2", approximately 7.5 mm in diameter

Spironolactone 50 mg film-coated tablets are white to off-white, round, biconvex tablets debossed on one side with “S3”, approximately 9 mm in diameter

Spironolactone 100 mg film-coated tablets are white to off-white, round, biconvex tablets debossed on one side with “S4”, approximately 12 mm in diameter

Spironolactone 12.5 mg film-coated tablets come in PVC/foil blister packs containing 100 or 500 tablets and PVC/foil of 28 tablets.

Spironolactone 25 mg film-coated tablets come in PVC/foil blister packs containing 100 or 500 tablets and PVC/foil of 28 tablets.

Spironolactone 50 mg film-coated tablets come in PVC/foil blister packs containing 100 or 500 tablets and PVC/foil of 28 tablets.

Spironolactone 100 mg film-coated tablets come in PVC/foil blister packs containing 100 or 500 tablets and PVC/foil of 28 tablets.

Not all packs may be marketed.

Marketing Authorisation Holder

Mercury Pharmaceuticals Limited

Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

Manufacturer:

Key Pharmaceuticals Ltd.

Galen House, 83 High Street, Somersham,

Cambridgeshire, PE28 3JB, UK.

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