

## Spirolactone 25mg, 50mg and 100mg tablets

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 Spirolactone tablets are and what they are used for
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#### 1 What Spirolactone tablets are and what they are used for

Spirolactone tablets belong to a group of medicines called potassium-sparing diuretics (water tablets), which help you lose excess fluid from your body. They may be used for:

- congestive heart failure
- nephrotic syndrome (a kidney disorder)
- liver cirrhosis with fluid retention (oedema) and swelling of the abdomen (ascites)
- a cancerous disease with swelling of the abdomen (malignant ascites)
- diagnosis and treatment of primary aldosteronism (a condition where excess hormone is produced).

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

#### 2 What you need to know before you take Spirolactone tablets

**Do not take** Spirolactone tablets and **tell** your doctor if **you:**

- are **allergic** to spiro lactone or any of the other ingredients of this medicine (listed in section 6)
- have **Addison's disease** (weakness, loss of energy, low blood pressure and dark pigmentation of the skin)
- have **severe kidney disease**
- have **high blood levels of potassium**
- are **not passing** urine
- are **breast-feeding**
- are taking **water tablets** (potassium sparing diuretics) or any potassium supplements
- are taking **eplerenone** (a medicine for high blood pressure).

Children with moderate to severe kidney disease must not take Spirolactone tablets.

### Warnings and precautions

**Talk to your doctor or pharmacist** before taking Spirolactone tablets if you:

- have a disease that can result in **electrolyte balance disturbance** in your blood such as **potassium** or **sodium**
- have **severe heart failure**
- are **pregnant**
- have **liver cirrhosis**
- have been passing **small amounts** of urine
- have a **severe illness**
- have ever had **too much acid** in the body
- have an inherited disorder of the red blood pigment haemoglobin causing skin blisters, abdominal pain and nervous system disorders (**porphyria**)
- have abnormal **periods** or swollen **breasts**
- suffer from **kidney disease** especially children with hypertension or liver disease. Your doctor will routinely assess you particularly if you are elderly.

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 Spirolactone 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 Spirolactone tablets

**Tell your doctor or pharmacist** if you are taking, have recently taken or might take any other medicines. Especially:

- blood pressure lowering medicines (antihypertensives) such as ACE inhibitors (e.g. captopril or enalapril) and angiotensin-II receptor antagonists (such as valsartan or losartan)
- chlorpropamide (used in diabetes)
- digoxin (used in some heart conditions)
- ciclosporin or tacrolimus (used to prevent organ transplant rejection, treat rheumatoid arthritis, eczema or psoriasis)
- fludrocortisone (a corticosteroid)
- warfarin (used to thin the blood)
- other potassium-sparing diuretics (water tablets)
- lithium (used for some mental illnesses)
- non-steroidal anti-inflammatory drugs (NSAIDs) such as indometacin and mefenamic acid
- aspirin to reduce pain, inflammation and high temperature
- potassium supplements (potassium salts)
- noradrenaline (norepinephrine) (used for low blood pressure or heart problems)
- an anaesthetic
- carbenoxolone (an ulcer healing drug)
- trimethoprim and trimethoprim-sulfamethoxazole.

### 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 for advice before taking this medicine. Spirolactone tablets should not be taken if you are breast-feeding.

### Driving and using machines

Spirolactone tablets may cause dizziness or drowsiness. Make sure you are not affected before you drive or operate machinery.

### Spirolactone 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 medicinal product, as it contains a type of sugar called lactose.

## Tests

Your doctor may want to carry out tests to monitor the levels of fluid and chemicals in your body, especially if you are elderly or have impaired liver or kidney function.

## 3 How to take Spironolactone tablets

Always take this medicine exactly as your doctor 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 (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include drowsiness, mental confusion, feeling or being sick, dizziness, diarrhoea, decreased blood levels of sodium, increased blood levels of potassium (symptoms include pins and needles or tingling, unusual tiredness or weakness, muscular weakness, paralysis with a loss of muscle tone, muscle spasm) and may have skin rashes that will appear as flat red areas of skin with overlapping small raised bumps.

### If you forget to take Spironolactone tablets

If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time. Do not take a double dose to make up for a forgotten dose.

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.

**Stop taking Spironolactone and contact your doctor at once** if you develop **high blood levels of potassium** (muscle twitching or weakness, irregular heart beat, unusual tiredness or weakness, paralysis with or without loss of muscle tone, circulatory failure), especially if you have impaired kidney function or a diet high in potassium.

**Contact your doctor immediately** if you experience the following:

- **an allergic reaction** (hypersensitivity) such as swelling of the face, lips, tongue or throat, difficulty breathing or swallowing, shock, collapse, skin rash or itching.
- severe form of skin rash with flushing, fever, blisters or ulcers (**Stevens-Johnson syndrome**)
- severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (**toxic epidermal necrolysis**)
- **Drug Reaction with Eosinophilia and Systemic Symptoms** (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature, enlarged lymph nodes, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia).

**Tell your doctor or pharmacist if you notice any of the following side effects,** they get worse or if you notice anything not listed:

- **Blood:** increase in blood levels of nitrogen or urea especially in those with impaired kidney function, altered numbers and types of blood cells. If you notice increased bruising, nosebleeds, sore throats or infections, you should tell your doctor who may want you to have a blood test.
- **Metabolism and nutrition:** low blood levels of sodium, changes in the levels of chemicals in the body.
- **Nervous system:** lack of muscle control or coordination, drowsiness, dizziness, headache, clumsiness.
- **Psychiatric:** tiredness, confusion.
- **Liver:** impaired liver function, a poisonous effect on the liver.
- **Stomach and intestines:** stomach upset, inflammation of the stomach lining, bleeding in the stomach, stomach or intestinal ulcers, stomach cramps, diarrhoea, feeling or being sick.
- **Skin:** skin rashes including pale or red irregular raised patches with severe itching (hives), hair loss, excessive hair growth, itching, rash, pemphigoid (condition presenting with fluid-filled blisters on the skin).
- **Muscle and bone:** bone softening due to vitamin D deficiency, leg cramps.
- **Kidneys:** acute kidney failure particularly in those who already have impaired kidney function.
- **Reproductive system:** enlarged breasts in men, changes in voice pitch, reduced sexual potency in men, changes in sexual ability/drive, breast tenderness, breast lumps and increased hair growth in females, irregular periods, sweating.
- **Other:** feeling of general discomfort and illness.

### 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](http://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 the sight and reach of children.

Do not store above 25 °C.

Store in the original package.

Keep container in the outer carton.

Do not use this medicine after the expiry date which is stated on the label/carton/bottle. 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 (the ingredient that makes the tablets work) is spironolactone. Each tablet contains either 25mg, 50mg or 100mg of the active substance.
- The other ingredients are lactose, magnesium stearate, maize starch, microcrystalline cellulose, peppermint flavour, polyvidone, sodium starch glycolate, purified water, iron oxide red (E172), iron oxide yellow (E172), methylhydroxypropylcellulose (E5) (E464), propylene glycol, titanium dioxide (E171).

### What Spironolactone tablets look like and contents of the pack

Spironolactone tablets are buff, circular, biconvex film-coated tablets.

Pack size is 28.

### Marketing Authorisation Holder and Manufacturer

Accord, Barnstaple, EX32 8NS, UK.

This leaflet was last revised in January 2020

**If you would like a leaflet with larger text, please contact 01271 385257.**