**Spironolactone 25mg, 50mg and 100mg tablets**

**What Spironolactone tablets are and what they are used for**

Spironolactone 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)
- a hereditary disease causing skin blisters, abdominal pain and nervous system disorders (porphyria)
- a condition where excess hormone is produced.

**What you need to know before you take Spironolactone tablets**

Do not take Spironolactone tablets and tell your doctor if you:

- are allergic to spironolactone or any of the other ingredients of this medicine listed in section 6.
- have diabetes with or without kidney problems.
- have Addison's disease (weakness, loss of energy, low blood pressure and dark pigmentation of the skin).
- have kidney problems which may be severe or worsening.
- have high blood levels of potassium.
- have impaired liver or kidney function.
- are not passing urine.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Spironolactone tablets if you have:

- a diet high in potassium.
- low blood levels of sodium.
- liver cirrhosis.
- been passing small amounts of urine.
- a severe illness.
- or have ever had too much acid in the body.
- an inherited disorder of the red blood pigment haemoglobin causing skin blisters, abdominal pain and nervous system disorders (porphyria).
- abnormal periods or swollen breasts.

**Possible 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. See section 4.

**How to store Spironolactone tablets**

Keep this medicine out of the reach of children.

Store it in a cool place, away from direct heat and sunlight.

Do not store it above room temperature.

Do not put it in the fridge or freezer.

Do not throw away any medicine that is outdated or no longer needed. Dispose of in the trash.

**What is in this leaflet**

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

**Other medicines and Spironolactone 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 heart conditions).
- ciclosporin or tacrolimus (used to prevent organ transplant rejection, treat rheumatoid arthritis, eczema or psoriasis).
- fluoroquinolones (e.g. ciprofloxacin or levofloxacin).
- 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).
- notodraline (norepinephrine) (used for low blood pressure or heart problems).
- an anaesthetic.
- carbamazepine (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. Spironolactone tablets should not be taken if you are breast-feeding.

**Driving and using machines**

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

**Spironolactone tablets contain lactose**

If you have been told by your doctor that you have 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.

**Diabetic and liver function tests**

If you are to have liver function tests, you are to be tested for diabetes or need to have other tests related to diabetes, tell your doctor that you are taking Spironolactone tablets. Spironolactone tablets may need to be stopped at least three days before a diabetes test.
How to take Spironolactone tablets

Always take this medicine exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Swallow the tablets with water and preferably with food.

The recommended doses are:

- **Adults**
  - Congestive heart failure – 100mg a day. The maintenance dose is 25-200mg a day. In difficult or severe cases, up to a maximum of 400mg a day may be taken.
  - Nephrotic syndrome – 100-200mg a day.
  - Liver cirrhosis with fluid retention and swelling of the abdomen – 100-400mg a day. Your doctor will decide on the best maintenance dose for you.
  - A cancerous disease with swelling of the abdomen – 100-200mg a day. Your doctor will decide on the best maintenance dose for you. In severe cases up to a maximum of 400mg a day may be taken.
- **Primary aldosteronism diagnosis** – Long term: 400mg a day for 3-4 weeks.
- Short term: 400mg a day for 4 days.
- **Primary aldosteronism treatment** – 100-400mg a day in preparation for surgery. If surgery is not to be carried out, your doctor will decide on the best maintenance dose for you.
- **Elderly**
  - Your doctor will decide on the best dose for you. If you have severely impaired liver or kidney function, your doctor may prescribe a different dose.
- **Children**
  - Recommended starting dose is 1mg per kg of bodyweight a day, to be taken in divided doses. Your doctor will adjust the dose depending on the response to treatment. If necessary, the tablets may be crushed and dispersed in food or drink.

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).

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.

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).
- other:
  - severe tenderness, breast lumps and increased hair growth in females, irregular periods, sweating.
- Other:
  - feeling of general discomfort and illness.

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

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.

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, polyviolate, sodium starch glycolate, purified water, iron oxide red (E172), iron oxide yellow (E172), methylhydroxypropylcellulose (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

Actavis, Barnstaple, EX32 8NS, UK.

This leaflet was last revised in May 2018.

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