

# Spironolactone 25mg, 50mg and 100mg tablets

**Read all of this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

## Index

- 1 What Spironolactone tablets are and what they are used for**
- 2 Before you take**
- 3 How to take**
- 4 Possible side effects**
- 5 How to store**
- 6 Further information**

## 1 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)
- diagnosis and treatment of primary aldosteronism (a condition where excess hormone is produced).

## 2 Before you take

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

- are **allergic** (hypersensitive) to spironolactone or any of the other ingredients in Spironolactone tablets (see 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**
- are **not passing** urine.

**Check with 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**.

## Taking other medicines

Please **tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. 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).

## Pregnancy and breast-feeding

If you are pregnant or planning to become pregnant, speak to your doctor 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.

## Sugar intolerance

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, 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.

### 3 How to take

Always take Spironolactone tablets 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**.

#### Doses:

##### • 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 test: 400mg a day for 3–4 weeks. Short test: 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

Usual starting dose is 3mg 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 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 the 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.

### 4 Possible side effects

Like all medicines, Spironolactone tablets 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 notice signs of an **allergic reaction** (hypersensitivity) such as swelling of the face, lips, tongue or throat, difficulty breathing or swallowing, shock, collapse, skin rash or itching.

**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.
- **Liver:** a poisonous effect on the liver.
- **Stomach and intestines:** inflammation of the stomach lining, bleeding in the stomach, stomach or intestinal ulcers, stomach cramps, diarrhoea, being sick.
- **Skin:** skin rashes including pale or red irregular raised patches with severe itching (hives), hair loss.
- **Muscle and bone:** bone softening due to vitamin D deficiency.
- **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, decreased sexual ability, breast tenderness and increased hair growth in females, irregular periods, sweating.

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

### 5 How to store Spironolactone tablets

Keep out of the reach and sight of children.

Do not store above 25 °C.

Store in the original package.

Keep container in the outer carton.

Do not use Spironolactone tablets after the expiry date which is stated on the label/carton/bottle. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### 6 Further 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

Actavis, Barnstaple, EX32 8NS, UK.

This leaflet was last revised in March 2008.



If you would like a leaflet with larger text, please contact 01271 311257.



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