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.

**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 too much hormone is produced).

**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 inherent 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**
- severe hyperkalaemia might include muscle cramps, irregular heart rhythm, diarrhoea, nausea, dizziness or headache.

**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)
- hydrocortisone (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 indomethacin 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
- carbamazepine (an ulcer healing drug)
- trimethoprim and trimethoprim-sulfamethoxazole.

**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.
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.

Dosage:
- 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, muscle 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.

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 heartbeat, 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)
- severe rash involving fever and swelling

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.
- 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, decreased sexual ability/drive, breast 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 notice 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

By reporting side effects you can help provide more information on the safety of this medicine.

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 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.

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, polysorbate 60, sodium starch glycolate, purified water, iron oxide red (E172), iron oxide yellow (E172), methylhydroxypropylcellulose (ES) (E464), propylene glycol, titanium dioxide (E171).

What Spironolactone tablets look like and contents of the pack
Spironolactone tablets are buff, circular, biocomex film-coated tablets.
Pack size is 28.
Marketing Authorisation Holder and Manufacturer
Actavis, Barnstaple, EX32 8NS, UK.
This leaflet was last reviewed in July 2017

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

Spironolactone Tablets all strengths x 28’s (UK)
JDE No: 50937977
Dimensions: 148x210 (Reel Fed)
Component: Leaflet for Blisters
Pharmacode: 2905
Date Sent: 17/07/17
Technologist: R.Wrey

Technically Approved

Actavis BST - Packing Technical
BSTCutterGuideReq@actavis.com

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