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Spironolactone All strengths Tablets PIL - UK

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**What is in this leaflet**

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).

   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 and tell your doctor if you:
   - are allergic to spironolactone 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 splanonone (a medicine for high blood pressure).

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

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

- If you already take any other medicines (including those bought without a prescription from a pharmacy).
- If you have ever had or are currently suffering from:
  - skin blisters, abdominal pain and nervous system disorders (severe skin disease. Your doctor will routinely assess you particularly if you are elderly.
  - 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 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. 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)
  - diuretics (used to prevent organ transplant rejection, treat rheumatoid arthritis, eczema or psoriasis)
  - fludrocortisone (a corticoesteroid)
  - 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 salt)
  - nonsteroidal (non-sodium) (used for low blood pressure or heart problems)
  - an anesthetic
  - carbamazepine (an ulcer healing drug)
  - trimethoprim and trimethoprim-sulfamethoxazole.

**Pregnancy and breast-feeding**

- If you are pregnant or breast-feeding, tell your doctor or pharmacist 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 an intolerance to some of the substances in this medicine. Spironolactone tablets contain lactose and 3% of sucrose.
- Children and adults who are breast-feeding.
- If you have ever had periods
- If you are planning to have a baby, ask your doctor for advice before taking this medicine.
- If you have ever had severe illness
- You may have an intolerance to some of the substances in this medicine. Spironolactone tablets contain lactose and 3% of sucrose.
- If you have ever had too much acid in the body
- If you have ever had an inherited disorder of the red blood pigment haemoglobin causing skin blisters, abdominal pain and nervous system disorders (porphyria)
- If you have abnormal periods or swollen breasts
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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.

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.

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 has swallowed any, contact your nearest hospital casualty department or your doctor immediately. Symptoms of an overdose include drowsiness, mental confusion, feeling or being sick, dizziness, diarrhoea, feeling or being sick.

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.

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, paralytic 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, blistering; 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, pustules (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 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.

How to store Spironolactone tablets
Keep out of the sight and reach of children.
Do not store above 25 ºC.
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.

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 stearyl glycolate, purified water, iron oxide red (E172), iron oxide yellow (E172), methyl hydroxypropylcellulose (E464), propylene glycol, titanium dioxide (E171).

What Spironolactone tablets look 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, EX2 8NS, UK.

This leaflet was last revised in January 2020

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