

PATIENT INFORMATION LEAFLET

SPIRONOLACTONE 25mg 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, please 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.**
- **If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

IN THIS LEAFLET

1. What your medicine is and what it is used for
2. Before you take your medicine
3. How to take your medicine
4. Possible side effects
5. How to store your medicine
6. Further information

1. WHAT YOUR MEDICINE IS AND WHAT IT IS USED FOR

The name of your medicine is Spironolactone 25mg Tablets or Spironolactone 100mg Tablets. It contains the active ingredient spironolactone. This belongs to a group of medicines called potassium sparing diuretics (water tablets). It works by helping you pass more water (urine) than you usually do.

Spironolactone Tablets are used for the treatment of:

- ascites and oedema (swelling in the abdomen due to fluid retention) associated with liver disease (cirrhosis) or malignant disease
- nephrotic syndrome (a kidney disease that causes too much fluid in your body)
- diagnosis and treatment of a hormone condition called primary aldosteronism (excessive production of aldosterone, a steroid produced by the adrenal gland)
- congestive heart failure (inability of the heart to pump blood around the body, resulting in swelling of veins and organs with blood)

2. BEFORE YOU TAKE YOUR MEDICINE

Do NOT take Spironolactone Tablets and tell your doctor if you:

- are allergic (hypersensitive) to spironolactone or any of the other ingredients in this medicine. Signs of an allergic reaction include a rash, itching, difficulty breathing or swelling of the lips, face, throat or tongue
- have a problem urinating (passing water)
- suffer from severe kidney problems
- suffer from Addison's Disease (this is when the adrenal glands do not work properly. It can cause weakness, tiredness, weight loss and low blood pressure)

- have high potassium levels in the blood (hyperkalaemia)
- have diabetes mellitus with or without kidney problems

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor before taking Spironolactone Tablets.

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Take special care with Spironolactone

Before you take Spironolactone Tablets tell your doctor if you:

- suffer from disturbances of blood chemicals e.g. potassium, calcium, chloride and urea (detected in blood tests)
- are a woman who has irregular periods
- have swollen breasts
- have too little sodium in the blood (hyponatraemia)
- suffer from porphyria – a generic disorder of red blood cell pigment (symptoms include stomach pain, seizures, vomiting, hallucinations, fast heart rate)
- suffer from kidney or liver disease
- suffer from serious respiratory disorders
- suffer from diarrhoea
- have recently had surgery or you are seriously ill
- have small urine production, this may be a sign of a kidney disorder
- are elderly

Long-term use of Spironolactone Tablets is not advised in young patients. Your doctor will decide whether this medicine is suitable for you. If any of the above apply to you, talk to your doctor or pharmacist before taking Spironolactone Tablets.

Tests

Tell your doctor or nurse you are taking Spironolactone Tablets if you are going to have an operation or a blood test. This is because this medicine can affect the results of some blood tests, such as liver tests or tests to measure blood levels of certain other drugs e.g. digoxin. You may need to stop taking this medicine before your operation or blood test.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines without a prescription, including herbal medicines.

In particular tell your doctor if you are taking any of the following:

- other diuretic drugs (water tablets), e.g. furosemide
- medicines or supplements containing potassium, e.g. Lo-salt
- cardiac glycosides e.g. digoxin (used to treat heart conditions)

- ciclosporin or tacrolimus (drugs used to prevent organ transplant rejection, treat rheumatoid arthritis, eczema or psoriasis)
- corticosteroids (used to treat Addison's disease, e.g. fludrocortisone)
- medicines used to treat high blood pressure (e.g. ACE inhibitors, angiotensin II receptor antagonists, diuretics, calcium channel blockers and other blood pressure lowering drugs))
- anti-diabetics (used to treat diabetes, e.g. chlorpropamide)
- anti-coagulants (drugs used to thin the blood, e.g. warfarin)
- lithium (used to treat mental illness, e.g. mania and bipolar disorders)
- mitotane (a drug used to treat cancer of the adrenal gland)
- carbenoxolone (used to treat stomach ulcers)
- colestyramine (used to treat high cholesterol)
- the contraceptive pill
- non-steroidal anti-inflammatory drugs (NSAIDs) (used to relieve pain, inflammation and stiffness, e.g. indometacin and diclofenac)
- aspirin
- antibiotics (used to treat infections, e.g. lymecycline)

Tell your doctor if you are due to have an anaesthetic.

Pregnancy and breast-feeding

Always talk to your doctor before taking any medicine if you are pregnant, planning to become pregnant or are breast-feeding. Breast-feeding is not recommended while taking Spironolactone Tablets. Always check with your doctor if you are not sure.

Driving and using machines

Spironolactone Tablets can cause drowsiness and dizziness. Patients should make sure they are not affected when driving or operating machinery.

HOW TO TAKE YOUR MEDICINE

Take this medicine exactly how your doctor or pharmacist has told you to. Always ask your doctor or pharmacist's advice if you are not sure.

Taking this medicine

- Take this medicine by mouth.
- Swallow these tablets with water and preferably food.

ADULTS

Congestive heart failure

The usual dose for adults is 100mg daily. To control the condition the usual dose is 25mg- 200mg daily. The maximum daily dose is up to 400mg daily.

Nephrotic syndrome

The usual dose for adults is 100mg-200mg daily.

Liver cirrhosis (liver disease)

The usual dose for adults is 100mg-400mg daily depending on your condition.

Swollen abdomen

The usual dose for adults is 100mg-200mg daily. The maximum daily dose is up to 400mg daily.

Diagnosis of primary aldosteronism

Long test: the usual daily dose is 400mg for 3-4 weeks.

Short test: the usual daily dose is 400mg for 4 days.

Treatment of primary aldosteronism

The usual adult dose is 100mg-400mg in preparation for surgery. If surgery is not suitable your doctor will decide a suitable dose to control the condition.

ELDERLY

Your doctor may prescribe a different dose to those above, depending on your liver or kidney function and response to treatment.

CHILDREN

The number of tablets you give your child will depend on your child's weight and response to treatment. The usual dose is 3mg per kg of body weight daily in divided doses. Tablets may be crushed and dispersed in food or drink if necessary. Speak to your doctor before giving this medicine to your child.

Always follow your doctor's advice about when and how to take your medicine and always read the label. Your pharmacist may be able to help if you are not sure.

If you take more of your medicine than you should

If you (or somebody else) accidentally take too much medicine, contact your nearest hospital casualty department, doctor or pharmacist immediately. Symptoms of an overdose include drowsiness, confusion, nausea, vomiting, dizziness or diarrhoea.

If you forget to take your medicine

If you do forget to take your medicine at the correct time, take it as soon as you remember, then carry on as before. Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking your medicine

Keep taking this medicine until your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the medicine, your condition may re-occur or get worse.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

POSSIBLE SIDE EFFECTS

Like all medicines, Spironolactone Tablets can have side effects although not everybody gets them.

If you have an allergic reaction to Spironolactone Tablets see a doctor IMMEDIATELY. An allergic reaction may include:

- skin rash, swelling of the face, lips, throat or tongue, difficulty breathing or swallowing. This is a very serious but rare side effect. You may need urgent medical attention.

If you get any of the following side effects, stop taking your medicine and see your doctor as soon as possible:

- **Effects on the blood:** blood disorders including changes in the number and types of white blood cells. Symptoms may include bruising, sore throats, nosebleeds or infections.
- **Effects on metabolism and nutrition:** hyponatraemia (too little sodium in the body) or hyperkalemia (too much potassium in the blood)
- **Effects on the nervous system:** loss of co-ordination or muscle control causing clumsiness, drowsiness, dizziness, headache
- **Effects on mental health:** feeling weak or tired, confusion
- **Effects on the heart:** too much potassium in the blood might cause muscle cramps or pain, irregular heartbeat, tiredness or weakness. In patients with kidney disease this type of reaction can be very serious. You should see your doctor IMMEDIATELY.
- **Effects on the liver:** liver damage which might cause jaundice (yellowing of the skin and whites of the eyes)
- **Effects on the stomach:** stomach upset, diarrhoea and constipation, vomiting (which may be bloody) and stomach ulcers
- **Effects on the skin:** skin rashes, itching, hives, alopecia or hair loss
- **Effects on the kidneys:** kidney failure
- **Effects on the reproductive system:** enlargement of the male breast, breast tenderness, unwanted hair growth in females or deepening of the voice, irregular menstrual cycles (periods), change in sexual drive and function, impotence (unable to maintain erection), sweating

If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting 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. 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.

NOTE: Spironolactone Tablets are not recommended for long-term use. Please talk to your doctor if you have any concerns about the length of time that you need to take these tablets.

HOW TO STORE YOUR MEDICINE

Do not use Spironolactone Tablets after the "expiry date" printed on the label or carton. The expiry date refers to the last day of that month.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Store below 25°C in a dry place. Protect from light. 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 protect the environment.

FURTHER INFORMATION

What Spironolactone Tablets contain

- The active ingredient is spironolactone.
- Spironolactone 25mg Tablets contain the following other ingredients: maize starch, magnesium stearate, calcium sulphate dihydrate, pre-gelatinized maize starch, crospovidone, povidone, quinoline yellow (E104) and peppermint flavour.
- Spironolactone 100mg Tablets contain the following other ingredients: maize starch, magnesium stearate, calcium sulphate dihydrate, pre-gelatinized maize starch, crospovidone, povidone, sodium starch glycollate, quinoline yellow (E104) and peppermint flavour.

What Spironolactone Tablets look like and contents of the pack

Spironolactone 25mg Tablets are biconvex, pale yellow tablets with a slight peppermint odour. "SPLN 25" is marked around the face of the tablet.

Spironolactone 100mg Tablets are biconvex, pale yellow tablets with a slight peppermint odour. "SPLN 100" is marked around the face of the tablet.

Spironolactone 100mg Tablets are available in blister packs containing 28 tablets and pots containing 28, 30, 56, 60, 84, 90, 100, 112 and 500 tablets.

Spironolactone 25mg Tablets are available in pots containing 28, 30, 56, 60, 84, 90, 100, 112 and 500 tablets. Not all pack types or pack sizes may be marketed.

Marketing Authorisation Holder

Relonchem Limited, Cheshire House, Gorsey Lane, Widnes, WA8 0RP, UK.

Manufacturer responsible for release of this medicine

Relonchem Limited, Cheshire House, Gorsey Lane, Widnes, WA8 0RP, UK.

This leaflet was last revised in June 2015