

Package leaflet: Information for the user

**SPIRONOLACTONE 25MG TABLETS**  
**SPIRONOLACTONE 100MG TABLETS**  
(Spironolactone)

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet (see section 4).

**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

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

- The active ingredient is Spironolactone. Spironolactone belongs to a group of medicines called ‘diuretics’ - you may know these as ‘water’ tablets. You may have gone to your doctor because you had swollen ankles or were short of breath. This can happen when your heart's pumping action has become weak because of too much fluid in your body. This is called ‘congestive heart failure’. Pushing extra fluid around your body means your heart has to work harder. Your doctor has given you Spironolactone to help you lose the extra fluid from your body. This will mean your heart has to do less work. You lose the extra fluid as urine, so you may need to go to the toilet more often while you are taking Spironolactone.

You can also take Spironolactone for the following illnesses:

- ‘Nephrotic syndrome’- a kidney disorder that causes too much fluid in your body
- ‘Ascites’ - too much fluid in your abdomen and ‘oedema’ -accumulation of fluid beneath skin or in one or more cavities of the body that produces swelling, for example caused by cirrhosis of the liver
- ‘Malignant ascites’- fluid containing cancer cells that collect in the abdomen
- ‘Primary aldosteronism’ - extra fluid in your body caused by too much of a hormone called ‘aldosterone’.

If you have these illnesses, Spironolactone will help your body to get rid of the extra fluid. Children should only be treated under guidance of a paediatric specialist.

You must talk to a doctor if you do not feel better or if you feel worse.

**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) signs of an allergic reaction include a rash, itching, difficulty breathing or swelling of the lips, face, throat or tongue
- suffer from anuria (absence of urine production) or you cannot pass urine
- have kidney problems which may be severe or worsening
- have Addison’s disease (a hormone deficiency characterised by extreme weakness, loss of weight, loss of energy, low blood pressure and dark pigmentation of the skin)
- have high potassium levels in the blood (hyperkalaemia)
- have diabetes mellitus with or without kidney problems
- are breast-feeding
- are taking water tablets (potassium sparing diuretics) or any potassium supplements
- are taking eplerenone (a medicine for high blood pressure)

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

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.

**Warnings and precautions**

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

- suffer from disturbances of blood chemicals e.g. potassium, calcium, chloride and urea (detected in blood tests)
- have abnormal periods or swollen breasts
- have ever had too much acid in the body
- 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 disease especially children with hypertension or liver disease.
- experienced breathing or lung problems (including inflammation or fluid in the lungs) following Spironolactone intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking spironolactone, seek medical attention immediately. Your doctor will routinely assess you particularly if you are elderly.
- have difficulty passing urine
- have severe heart failure
- liver cirrhosis
- 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
- are pregnant

- you have a disease that can result in electrolyte balance disturbance in your blood such as potassium or sodium
- are taking any other water tablets (diuretics) in combination with spironolactone which may cause low sodium levels
- have a diet rich in potassium or salt substitutes containing potassium

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.

Long-term use of Spironolactone Tablets is not advised in young patients. Your doctor will decide whether this medicine is suitable for you.

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 can be fatal.

If any of the above apply to you, talk to your doctor or pharmacist before taking Spironolactone Tablets.

**Tests**

Tell your doctor or nurse that you are taking Spironolactone Tablets if you are going to have 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.

**Other medicines and Spironolactone tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor may wish to alter your dose of Spironolactone if you are taking any of the following:

- other potassium-sparing 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)
- blood pressure lowering medicines (antihypertensives) such as ACE inhibitors (eg. captopril or enalapril), angiotensin II receptor antagonists (such as valsartan or losartan), diuretics and calcium channel blockers)
- anti-diabetics (used to treat diabetes, e.g. chlorpropamide)
- anti-coagulants (drugs used to thin the blood, e.g. warfarin, Heparin, low molecular weight heparin)
- lithium (used to treat mental illness, e.g. mania and bipolar disorders)
- carbenoxolone (used to treat stomach ulcers)
- colestyramine (used to treat high cholesterol)
- the contraceptive pill
- Potassium supplements

- non-steroidal anti-inflammatory drugs (NSAIDs) (used to relieve pain, inflammation and stiffness, e.g. indometacin, aspirin, mefenamic acid or ibuprofen and diclofenac)
- trimethoprim and trimethoprim-sulfamethoxazole
- aspirin to reduce pain, inflammation and high temperature
- antipyrene
- noradrenaline (norepinephrine) (used for low blood pressure or heart problems)
- medicines known to cause hyperkalaemia (raised blood potassium levels)
- an anaesthetic

Spironolactone reduces your responsiveness to noradrenaline. If you are going to have an operation where you will be given an anaesthetic, tell the doctor in charge that you are taking Spironolactone Tablets.

**Tell your doctor, if you are using abiraterone for treatment of prostate cancer.**

Tell your doctor, if you are using mitotane for treatment of malignant tumours of the adrenal glands. This medicine should not be used together with mitotane.

**Pregnancy, breast-feeding and fertility**

**Pregnancy**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There are limited data from the use of spironolactone in pregnant women. Your doctor will only prescribe Spironolactone if the potential benefit outweighs the potential risk.

**Breast-feeding**

Spironolactone Tablets should not be used if you are breast-feeding. You should discuss the use of Spironolactone Tablets with your doctor, who will advise you to consider an alternative method of feeding your baby while you are taking this medicine.

**Driving and using machines**

Take care if you drive or operate machinery.

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

**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.

**Spironolactone tablets contain Lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **Information on sodium content**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium free’.

### **3. How to take Spironolactone tablets**

Always take this medicine exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure. The pharmacist’s label on the pack also gives this information. The number of tablets you need to take depends on your illness.

#### **Taking this medicine**

- Take this medicine by mouth.
- Swallow these tablets with water and preferably with 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 with fluid retention and swelling of the abdomen**

The usual dose for adults is 100mg-400mg daily depending on your condition. Your doctor will decide on the best maintenance dose for you.

##### **A cancerous disease with swelling of the abdomen**

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

##### **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 forget to take Spironolactone tablets**

If you forget to take a dose at the correct time, take your Spironolactone tablets as soon as you remember, then go on as before. Do not take a double dose to make up for a forgotten dose

#### **If you take more Spironolactone tablets than you should**

If you (or somebody 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, doctor or pharmacist immediately. Symptoms of an overdose include drowsiness, feeling dehydrated, 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). You may also feel or be sick, suffer from diarrhoea and may have skin rashes that will appear as flat red areas of skin with overlapping small raised bumps.

#### **If you stop taking Spironolactone tablets**

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, pharmacist or nurse.

### **4. 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.
- Itchiness and blistering of the skin around the lips and the rest of the body, red or purple rash spreading and forming blisters (**Stevens-Johnson syndrome**)
- Detachment of the top layer of skin from the lower layers of skin, all over the body (**toxic epidermal necrolysis**)
- a severe form of allergic reaction called **DRESS syndrome** which may show up with the following symptoms: fever, skin rash, joint pain, swelling of glands, abnormalities of blood including increase in blood cells called eosinophils, abnormalities of kidney and liver function.
- Irregular heartbeat which can be fatal, tingling sensation, paralysis (loss of muscle function) or difficulty in breathing, which may be symptoms of raised potassium levels in your blood. Your doctor will conduct regular blood tests to monitor potassium levels in your blood. Your doctor will conduct regular blood tests to monitor potassium and other

electrolyte levels. He or she may stop you treatment if necessary.

- Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion) (very rare).

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

- 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. This may be due to reduced number of cells that fight infection- white cells (leukopenia), reduced number of cells that help with clotting (thrombocytopenia)
- Low blood levels of sodium, changes in the levels of chemicals in the body.
- Lack of muscle control or coordination, drowsiness, dizziness, headache, clumsiness, tiredness, mental confusion, fever.
- Yellow skin and eyes (jaundice), spironolactone can cause impairment of liver function; Hepatotoxicity (a poisonous effect on the liver)
- Inflammation of the stomach lining, bleeding in the stomach, stomach or intestinal ulcers, stomach cramps, diarrhoea, being sick, stomach upset
- Skin rashes including pale or red irregular raised patches with severe itching (hives), hair loss, excessive hair growth, itching, nettle like rash, pemphigoid (condition presenting with fluid-filled blisters on the skin).
- Bone softening due to vitamin D deficiency, leg cramps.
- Acute kidney failure particularly in those who already have impaired kidney function.
- Enlarged breasts in men, changes in voice pitch, reduced sexual potency in men, decreased sexual ability, breast pain.
- Mild androgenic effects like breast tenderness, breast lumps, increased hair growth in females, change in sex drive in women, irregular periods, sweating, breast pain.
- general discomfort and illness
- Vomiting or feeling sick
- Digestion problems, stomach upset
- Disturbances in body electrolytes such as high blood calcium
- Hair loss

#### **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 Website: [www.mhra.gov.uk/yellowcard](http://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.

### **5. How to store Spironolactone tablets**

- Keep this medicine out of the sight and reach of children.

- Do not use this medicine after expiry date (EXP.) which is stated on the carton. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package in order to protect from light and moisture.
- Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. Contents of the pack and other information**

#### **What Spironolactone Tablets contain:**

- The active substance is Spironolactone.
- The other ingredients are: colloidal anhydrous silica, sodium lauryl sulfate, rice starch, lactose monohydrate, micro-crystalline cellulose, povidone, peppermint oil, industrial methylated spirit, magnesium stearate, methyl-hydroxy propylcellulose, polyethylene glycol, opaspray (E 171, E 464, E 172), talc. The 25mg tablets also contain agar.

#### **What Spironolactone Tablets look like and contents of the pack:**

- Spironolactone 25mg tablets are buff coloured, biconvex, film coated tablets marked ‘25’ on one side and ‘BL’ on the reverse.
- Spironolactone 100mg tablets are buff coloured, biconvex, film coated tablets marked ‘100’ on one side and ‘BL’ on the reverse.
- Spironolactone tablets are available in bottle packs of 21, 28, 100, 250, 500, 1000 tablets and blister pack of 28 tablets.
- Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturer**

Name and address:

Bristol Laboratories Ltd,  
Unit 3, Canalside, Northbridge Road, Berkhamsted,  
Hertfordshire, HP4 1EG, United Kingdom

Telephone: 0044 (0)1442 200922

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#### **Manufacturer**

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**Spironolactone 25mg Tablets; PL 17907/0330**

**Spironolactone 100mg Tablets; PL 17907/0331**

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