



## LEAFLET

# AGOLACTONE - 25

(Spironolactone Tablets BP)

Each uncoated tablet contains :  
Spironolactone BP 25 mg  
Excipients ..... q.s.

Spironolactone tablets belong to a group of medicines called potassium-sparing diuretics (water tablets), which help you lose excess fluid from your body.

### Indications:

- congestive heart failure AGOLACTONE -25 TABLETS
- nephrotic syndrome (a kidney disorder) ( Spironolactone Tablets BP )
- 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).

### Dosage & Administration:

#### Adults

**Congestive heart failure** – 100 mg a day. The maintenance dose is 25-200 mg 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 400 mg 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.

### Special Precaution:

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
- an inherited disorder of the red blood pigment haemoglobin causing skin blisters, abdominal pain and nervous system disorders (porphyria)
- abnormal periods or swollen breasts.

### Drug Interactions :

Consult the 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)



**AQOG Pharma Ltd.**



(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)

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#### **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.

#### **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.

#### **Oversdosage :**

If you take lot of tablets at the same time, or you think a child may have taken 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).

#### **Side effects :**

**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.

#### **Storage :**

Store under normal storage conditions (15°C to 30°C)

Protect from light.

Keep all medicines out of reach of children.

**Shelf life:** 36 month

#### **Presentation:**

Jar Pack of 1000 Tablets

Blister Pack of 10 X 10 Tablets



Manufactured in India by:

**AQOG PHARMA LTD.**

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