

Aldactone®

**Aldactone® 100mg and 25mg Tablets**

Spironolactone

Film coated tablets

UK

Common Export Pack

## **PACKAGE LEAFLET**

**Package leaflet: Information for the patient**

**Aldactone® 25mg Tablets**  
**Aldactone® 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet:**

1. What Aldactone is and what it is used for
2. What you need to know before you take Aldactone
3. How to take Aldactone
4. Possible side effects
5. How to store Aldactone
6. Contents of the pack and other information

### **1. What Aldactone is and what it is used for**

Aldactone contains the active substance spironolactone. Aldactone 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 Aldactone 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 Aldactone.

You can also take Aldactone 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, Aldactone will help your body to get rid of the extra fluid.

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

Children should only be treated under guidance of a paediatric specialist.

## 2. What you need to know before you take Aldactone

### Do not take Aldactone if:

- you are allergic to spironolactone or any of the other ingredients of this medicine (listed in section 6)
- you cannot pass urine
- you have severe kidney disease
- you have Addison's disease; (a hormone deficiency characterised by extreme weakness, loss of weight and low blood pressure)
- you have hyperkalaemia (raised blood potassium levels)
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- you are breast-feeding
- you are taking water tablets (potassium sparing diuretics) or any potassium supplements
- you are taking eplerenone (a medicine for high blood pressure).

Children with moderate to severe kidney disease must not take Aldactone.

### Warnings and precautions

Talk to your doctor or pharmacist before taking Aldactone if:

- you suffer from kidney disease especially children with hypertension or liver disease. Your doctor will routinely assess you particularly if you are elderly
- you have difficulty passing urine
- you have a disease that can result in electrolyte balance disturbance in your blood such as potassium or sodium
- you have severe heart failure
- you are pregnant

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 Aldactone 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 Aldactone

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription. Your doctor may wish to alter your dose of Aldactone if you are taking any of the following:

- digoxin or carbenoxolone
- medicines for high blood pressure including angiotensin-converting enzyme (ACE) inhibitors
- other diuretics

- non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin, indomethacin, mefenamic acid or ibuprofen
- potassium supplements
- heparin or low molecular weight heparin (medicines used to prevent blood clots)
- antipyrine
- medicines known to cause hyperkalaemia (raised blood potassium levels)
- trimethoprim and trimethoprim-sulfamethoxazole

Aldactone 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 Aldactone.

#### **Aldactone with food, drink and alcohol**

See section 3 'How to take Aldactone'.

#### **Pregnancy, breast-feeding and fertility**

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

Aldactone should not be used if you are breast-feeding. You should discuss the use of Aldactone 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. Drowsiness and dizziness have been associated with Aldactone treatment and this may affect your ability to drive or operate machinery safely.

### **3. How to take Aldactone**

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. 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.

#### **Children and adolescents**

If you are giving Aldactone 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 Aldactone than you should**

If you accidentally take too many tablets, contact your doctor or nearest hospital accident and emergency department immediately. The symptoms of an overdose are feeling drowsy, dizzy, feeling dehydrated and you may feel confused. 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. Changes in your blood sodium and potassium levels may leave you feeling weak and suffering from tingling, prickling or numbness of the skin and/or muscle spasms but these symptoms are unlikely to be associated with severe overdose.

#### **If you forget to take Aldactone**

If you forget to take your tablet, take it as soon as you remember, unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Aldactone**

It is important to keep taking Aldactone until your doctor tells you to stop, even if you start to feel better.

If you stop taking the tablets too soon, your condition may get worse.

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

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Tell your doctor immediately** if you experience any of the following symptoms after taking this medicine. Although they are very rare, the symptoms can be severe.

- Itchiness and blistering of the skin around the lips and the rest of the body (Stevens-Johnson syndrome)
- Detachment of the top layer of skin from the lower layers of skin, all over the body (toxic epidermal necrolysis)
- Skin rash, fever and swelling (which could be symptoms of something more serious, drug rash and eosinophilia and systemic symptoms)
- Yellow skin and eyes (jaundice), Aldactone can cause impairment of 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 and other electrolyte levels. They may stop your treatment if necessary.

### **Other side effects of Aldactone**

- Nausea, stomach upset
- Confusion, dizziness
- Menstrual problems in women
- Change in sex drive for both men and women (libido)
- Disturbances in body electrolytes
- Reduced number of cells that fight infection - white cells (leukopenia), reduced number of cells that help with clotting (thrombocytopenia)
- Excessive growth of breast tissue in men (gynaecomastia, this goes away when treatment is stopped), breast lumps, breast pain
- Skin rash, generalised itchiness
- Skin allergy with development of itchiness and weals (urticaria), excessive hair growth (hypertrichosis), skin condition presenting with fluid-filled blisters (pemphigoid)
- Hair loss
- General weakness, muscle or leg cramps
- Sudden kidney failure or abnormal liver function
- Raised potassium in the blood (hyperkalaemia)

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

### **5. How to store Aldactone**

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

Keep your tablets in a dry place, below 30°C.

Do not use Aldactone after the expiry date which is stated on the blister, carton or bottle label after EXP. 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 to protect the environment.

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

### **What Aldactone contains**

The active substance is spironolactone:

Each Aldactone 25mg tablet contains 25mg of spironolactone. Each Aldactone 100mg tablets contain 100mg spironolactone.

The other ingredients are calcium sulfate dihydrate, corn starch, polyvinylpyrrolidone, magnesium stearate, felcofix peppermint, hypromellose, polyethylene glycol and opaspray yellow (E171 and E172).

### **What Aldactone looks like and the contents of the pack**

The name of your medicine is Aldactone.

The Aldactone 25 mg tablets are buff, film coated tablets engraved "SEARLE 39" on one side.

The Aldactone 100mg tablets are buff, film coated tablets engraved "SEARLE 134" on one side.

Aldactone 25mg tablets come in packs of 50, 100, 500 and 1000 tablets.

Aldactone 100mg tablets come in packs of 50, 100, 500, 1000 and calendar packs of 28 tablets.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

Pfizer Limited

Ramsgate Road, Sandwich, Kent

CT13 9NJ

United Kingdom

### **Manufacturer**

Piramal Healthcare UK Limited

Morpeth, Northumberland

NE61 3YA

This leaflet was last revised in April 2016.

### **THIS IS A MEDICAMENT**

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
- The doctor and the Pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

**Keep all medicaments out of reach and sight of children**

**Council of Arab Health Ministers**

**Union of Arabic Pharmacists**