

PACKAGE LEAFLET: INFORMATION FOR THE USER

ALDACTONE

25mg and 50mg Film-coated tablets

SPIRONOLACTONE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

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

1. WHAT ALDACTONE IS AND WHAT IT IS USED FOR

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, for example caused by cirrhosis of the liver
- '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
- 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)
- you cannot pass urine
- you have severe kidney disease
- 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.
- you are pregnant
- you are taking any other water tablets (diuretics) in combination with Aldactone which may cause low sodium levels (hyponatraemia) in the blood
- you have a diet rich in potassium or salt substitutes containing potassium.

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

Please 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, indometacin, mefenamic acid or ibuprofen
- potassium supplements
- heparin or low molecular weight heparin (medicines used to prevent blood clots)
- antipyrine
- noradrenaline
- medicines known to cause hyperkalaemia (raised blood potassium levels)
- trimethoprim and trimethoprim-sulfamethoxazole

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

This medicine should be taken with food (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 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 200mg spironolactone a day. 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 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 department immediately. The symptoms of an overdose are feeling drowsy and dizzy. You may also feel or be sick or may suffer from diarrhoea.

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 missed 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, tingling sensation, paralysis 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. He or she 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 cramps
- Sudden kidney failure

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 this medicine after the expiry date which is stated on the carton 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.

This leaflet was last revised in 03/2016