

PACKAGE LEAFLET: INFORMATION FOR THE USER
Aldactone® 100mg, 50mg and 25mg Tablets
spironolactone

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, 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
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In this leaflet:

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

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.

2. BEFORE YOU TAKE ALDACTONE

Do not take Aldactone if:

- you have had an unusual or allergic reaction to spironolactone in the past
- 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) or any other conditions associated with hyperkalaemia
- 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).

Take special care with Aldactone if:

- you suffer from kidney 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.

Taking other medicines

Please tell your doctor if you are taking or have recently taken 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 ACE inhibitors
- other diuretics
- non-steroidal anti-inflammatory drug (NSAID) such as aspirin 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)

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.

Taking Aldactone with food or drink

This medicine should be taken with food (see section 3 'How to take Aldactone')

Pregnancy and Breast-feeding

Tell your doctor if you are pregnant, think you may be pregnant or are planning to become pregnant as your doctor will need to judge whether you should be prescribed Aldactone.

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 Aldactone exactly as your doctor has told you. You should 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.

Children

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Aldactone 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)
- Hair loss
- General weakness, muscle cramps
- Sudden kidney failure

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

5. How to store Aldactone

- Keep out of the reach and sight of children
- Keep your tablets in a dry place, below 30°C
- Don't take Aldactone after the 'expiry' date shown on the pack

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 to protect the environment.

6. FURTHER INFORMATION

What Aldactone contains

The active substance is spironolactone. Each Aldactone 25mg tablet contains 25mg of spironolactone. Aldactone 50mg tablets contain 50mg of spironolactone and Aldactone 100mg tablets contain 100mg spironolactone.

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

Aldactone 50mg contains opaspray white (E171) instead of opaspray yellow.

What Aldactone looks like and the content 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 50mg tablets are white, film-coated tablets engraved "SEARLE 916" 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 50mg tablets come in packs of 50, 100 and 500 tablets.

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

All pack sizes may not be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Pharmacia Limited,
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