Package leaflet: Information for the patient

Aldactone® 25 mg Film-coated Tablets
Aldactone® 50 mg Film-coated Tablets
Aldactone® 100 mg Film-coated 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

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.

Your doctor may also give you Aldactone if your blood pressure is higher than it should be. This is called ‘hypertension’. High blood pressure occurs when there is increased pressure of blood within the walls of your blood vessels. By taking fluid from within your blood vessels, Aldactone reduces the pressure on the walls of the blood vessels and so lowers your blood pressure.

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)
- if you have Addison's disease (a hormone deficiency characterised by extreme weakness, loss of weight and low blood pressure)
- if you have hyperkalaemia (raised blood potassium levels) or any other conditions associated with hyperkalaemia
- if you cannot pass urine
- if you have severe kidney disease
- if you are already taking another similar use drug known as eplerenone
- if you are taking water tablets (potassium sparing diuretics) or any potassium supplements
- if you are breast feeding.

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
- if you are an elderly patient or
- if you have difficulty passing urine, or
- if you have a disease that can result in electrolyte balance disturbance in your blood
  if you suffer from any increase or decrease of electrolytes in your blood such as potassium or sodium
- if you have severe heart failure
- 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
- if you are taking any other water tablets (diuretics) in combination with Aldactone which may cause low sodium levels (hyponatraemia) in the blood
- if you are pregnant.

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. The use of Aldactone with high potassium salt diet and salt substitutes containing potassium may lead to increased levels of potassium in your blood. Your doctor may wish to alter your dose of Aldactone if you are taking any of the following:

- ACE inhibitors, digoxin or other anti-arrhythmic medicines
- antipyrine, colestyramine, ammonium chloride or carbenoxolone
- medicines for high blood pressure including angiotensin-converting enzyme (ACE) inhibitors
- other diuretics
- non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin, ibuprofen or mefenamic acid
- potassium supplements
- noradrenaline
- cardiac glycosides, used in the treatment of heart failure
- regional or general anaesthesia
- anti-pyrines, used to reduce fever
- heparin (a medicine preventing blood clots forming)
- medicines known to cause hyperkalaemia (raised blood potassium levels)

- trimethoprim and trimethoprim-sulfamethoxazole

Spironolactone use can increase lithium concentration in your blood. Your doctor should monitor your blood-lithium levels regularly if you are taking both medications.

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.

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.

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

Pregnancy, breast-feeding and fertility
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.

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

Breast-feeding
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.

The recommended dose is once a day with food.

Use in adults
The adult dose varies from 25mg to 400mg spironolactone a day. If you are not sure how much to take, ask your doctor or pharmacist.

Use in the 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 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 over dosage.

If you forget to take Aldactone
Do not take a double dose to make up for a forgotten tablet. If you forget to take your tablet, take it as soon as you remember, unless it is almost time for your next 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, 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 - TEN)
- Skin rash, fever and swelling (which could be symptoms of something more serious, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- Yellow skin and eyes (jaundice; Aldactone can cause impairment of liver function)
- Irregular heartbeat that 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. He or she may stop your treatment if necessary.

List of other side effects of Aldactone by frequency:

Very common: may affect more than 1 in 10 people
- Raised potassium in the blood

Common: may affect up to 1 in 10 people
- Confusion
- Dizziness
- Feeling sick
- Itching of the skin
- Rash
- Muscle or leg cramps
- Kidney failure or abnormal function
- Breast enlargement in men
- Breast pain (in men)
- Feeling generally unwell

Uncommon: may affect up to 1 in 100 people
- Changes in the breast such as breast lumps
- Disturbances in body electrolytes such as high blood calcium
- Abnormal functioning of the liver
- Skin allergy with development of itchiness and hives, nettle like rash
- Menstrual problems in women

- Breast pain (in women)

Not known: frequency cannot be estimated from the available data
- Lowered white blood cell count in blood
- Reduced number of cells that fight infection –white blood cells which make infections more likely
- Reduced number of cells carrying oxygen (anaemia)
- Reduced number of cells that help with blood clotting or increased eosinophil count in the blood (eosinophilia) which increases risk of bleeding or bruising or causes purple spots on the skin (purpura)
- Change in sex drive for both men and women
- Temporary impotence in men
- Digestion problems, stomach upset
- Skin condition presenting with fluid-filled blisters (pemphigoid)
- Hair loss
- Excessive hair growth
- Headache
- Drowsiness
- General weakness or lethargy and problems coordinating muscle movements (ataxia)
- Fever

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
Ireland
HPRA Pharmacovigilance. Website: www.hpra.ie.

Malta
ADR Reporting
Website: https://medicinesauthority.gov.mt/adrportal

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.

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 store above 30°C.
Keep blisters in the outer carton in order to protect from light.

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 protect the environment.

6. Contents of the pack and other information

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

- The other ingredients are calcium sulfate dihydrate, maize starch, povidone, magnesium stearate, felcofix peppermint, hypromellose and macrogol 400. Aldactone 50mg contains titanium dioxide (E171). Aldactone 25mg and 100mg also contain titanium dioxide (E171), iron oxide yellow (E172) and iron oxide red (E172).

What Aldactone looks like and contents of the pack
The name of your medicine is Aldactone.
The Aldactone 25mg 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 film-coated tablets come in PVC/foil blister packs of 50 and 100 tablets.
Aldactone 50mg film-coated tablets come in PVC/foil blister packs of 50 and 100 tablets.
Aldactone 100mg film-coated tablets come in PVC/foil blister packs of 50 and 100 tablets and PVC/foil calendar packs of 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Ireland
Pfizer Healthcare Ireland Unlimited Company
The Watermarque Building
Ringsend Road,
Dublin 4,
D04 K7N3
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Malta
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Neo Psychiko 15451, Greece

Manufacturer
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2333 CW
Netherlands

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