

## **Package leaflet: Information for the patient**

**Aldactide® 25 mg/25 mg film-coated tablets**

**Aldactide® 50 mg/50 mg film-coated tablets**

(spironolactone and hydroflumethiazide)

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

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

Aldactide is a diuretic medicine (“water tablet”) used for the treatment of Congestive Heart Failure.

You may have gone to your doctor because of symptoms like swollen ankles and breathlessness. 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. This may lead to weakness. Your doctor has given you Aldactide 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 Aldactide.

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

#### **2. What you need to know before you take Aldactide**

##### **Do not take Aldactide if:**

- you are allergic to spironolactone, thiazide, diuretics or sulphonamides (a type of antibiotic) or any of the other ingredients of this medicine (listed in section 6)
- 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 have hypercalcaemia (raised blood calcium levels)
- you cannot pass urine
- you have severe kidney disease
- you are taking other potassium conserving diuretics or potassium supplements, which may induce hyperkalaemia

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Aldactide if:

- you suffer from liver disease
- you are pregnant

- you have diabetes, gout, systemic lupus erythematosus (lupus), or high blood fats, (such as high cholesterol)
- you are taking loop diuretics, glucocorticoids or adrenocorticotropic hormones (ACTH) as this may lead to profound diuresis and hypokalaemia (reduced blood potassium levels)
- you are taking other diuretics, which may cause hyponatraemia (reduced blood sodium levels)
- you have kidney problems
- you need your blood potassium levels to be monitored because you are taking other medicines which could cause you to lose too much body fluid
- you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to a week of taking Aldactide. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this
- you have a history of skin cancer

### **Other medicines and Aldactide**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor may wish to alter your dose of Aldactide if you are taking any of the following:

- digoxin, quinidine or other heart medicines
- lithium or carbenoxolone
- lipid-lowering medicines such as cholestyramine and colestipol
- medicines for high blood pressure such as angiotensin-converting enzyme (ACE) inhibitors or angiotensin II antagonists
- other diuretics
- non-steroidal anti-inflammatory drug (NSAIDs) such as aspirin, indometacin, mefenamic acid or ibuprofen
- mineral or vitamin supplements such as potassium, calcium or vitamin D
- medicines known to cause hyperkalaemia (raised blood potassium levels), such as aldosterone blockers
- medicines used to prevent blood clots such as heparin and low molecular weight heparin
- noradrenaline
- medicines to treat diabetes such as insulin
- corticosteroids
- medicines to treat gout, such as allopurinol and probenecid

If you are going to have an operation where you will be given an anaesthetic, tell the doctor in charge that you are taking Aldactide.

### **Tell your doctor, if you are using abiraterone for treatment of prostate cancer.**

#### **Aldactide with food or drink**

See section 3 **How to take Aldactide**

#### **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.

Aldactide should not be used if you are breast-feeding.

You should discuss the use of Aldactide 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. The treatment may affect your ability to drive or operate machinery safely.

### **3. How to take Aldactide**

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 label on the pack also explains this information. This medicine should be taken once a day with food.

#### **Adults**

The recommended adult dose is 100 mg once daily. However the dosage will be adjusted by your doctor as necessary and may range from 25 mg to 200 mg 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 Aldactide 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 Aldactide 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 Aldactide**

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 Aldactide**

Do not stop taking your tablets or alter the dose you are currently taking without seeing your doctor first, 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.

- 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
- 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), Aldactide can cause impairment of liver function
- Decreased urine output with puffy eyes (acute renal injury)
- Black discoloration of your extremities caused by necrotising vasculitis (gangrene caused by poor circulation)

**List of other side effects of Aldactide 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
- Vomiting or 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
- Headaches
- Indigestion, stomach pain
- Fever

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)
- Tingling, pins and needles
- Inflammation of the pancreas which causes severe pain in the abdomen and back
- Photosensitivity (a skin reaction caused by exposure to sunlight)

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 that help with blood clotting which increases risk of bleeding or bruising
- Change in sex drive for both men and women
- Digestion problems, stomach upset
- Hair loss
- Excessive hair growth
- Short-sightedness
- Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma)
- Breast enlargement
- Problems getting or keeping an erection
- Feeling faint on standing (postural hypotension), vertigo

- Feeling restless
- Abnormal colour vision (xanthopsia)
- Non-melanoma skin cancers

### **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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Aldactide**

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, bottle and blister after 'EXP'. The expiry date refers to the last day of that month.

Store below 30°C.

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 Aldactide contains**

The active substances are spironolactone and hydroflumethiazide. Each Aldactide 25 mg/25 mg tablet contains 25 mg of spironolactone and 25 mg of hydroflumethiazide. Each Aldactide 50 mg/50 mg tablet contains 50 mg of spironolactone and 50 mg of hydroflumethiazide.

The other ingredients are calcium sulfate dihydrate, corn starch, polyvinylpyrrolidone, magnesium stearate, Felcofix peppermint, hypromellose, polyethylene glycol and Opaspray yellow (contains iron oxides/hydroxides E171 and titanium dioxide E172).

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

The Aldactide 25 mg / 25 mg tablets are buff coloured, film coated tablets, approximately 9.5 mm in diameter and engraved with "SEARLE 101" on one side.

The Aldactide 50 mg/50 mg tablets are buff coloured, film coated tablets, approximately 10 mm in diameter and engraved with "SEARLE 180" on one side.

Both Aldactide 25 mg/25 mg and 50 mg/50 mg tablets come in packs of 100 and 500 tablets. Aldactide 50 mg/50 mg tablets also come in calendar packs of 28 tablets. Not all pack sizes may be marketed.

### **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  
United Kingdom

Company Contact address

For further information on this medicine, please contact Medical Information at Pfizer Limited,  
Walton Oaks, Tadworth, Surrey, KT20 7NS, United Kingdom, Tel: +44 1304 616161

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