ALDACTONE®

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1. NAME OF THE MEDICINAL PRODUCT

Aldactone®

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: spironolactone 25 mg.

3. PHARMACEUTICAL FORM

Tablets are for oral administration.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Spironolactone is indicated for the following:

- Congestive cardiac failure.
- Hepatic cirrhosis with ascites and edema.
- Malignant ascites.
- Nephrotic syndrome.
- Diagnosis and treatment of primary hyperaldosteronism.

4.2 Posology and method of administration

Administration of spironolactone once daily with a meal is recommended.

Adults
Congestive cardiac failure
The usual dosage is 100 mg/day. In difficult or severe cases, the dosage may be gradually increased up to 400 mg/day. When edema is controlled, the usual maintenance level is 75 mg/day to 200 mg/day.

Hepatic cirrhosis with ascites and edema
If urinary Na^+/K^+ ratio is greater than 1.0, the usual adult dose is 100 mg/day. If the ratio is less than 1.0, the usual adult dose is 200 mg/day to 400 mg/day. Maintenance dosage should be individually determined.

Malignant ascites
Initial dose is usually 100 mg/day to 200 mg/day. In severe cases the dosage may be gradually increased up to 400 mg/day. When edema is controlled, maintenance dosage should be individually determined.

Nephrotic syndrome
The usual adult dose is 100 mg/day to 200 mg/day. Spironolactone has not been shown to be anti-inflammatory, or to affect the basic pathological process. Its use is only advised if glucocorticoids by themselves are insufficiently effective.

Diagnosis and treatment of primary hyperaldosteronism
Spironolactone may be employed as an initial diagnostic measure to provide presumptive evidence of primary hyperaldosteronism while patients are on normal diets.

Long test: Daily adult dose of 400 mg for 3 to 4 weeks. Correction of hypokalemia and hypertension provides presumptive evidence for the diagnosis of primary hyperaldosteronism.

Short test: Daily dosage of 400 mg for 4 days. If serum potassium increases during spironolactone administration, but drops when spironolactone is discontinued, a presumptive diagnosis of primary hyperaldosteronism should be considered.

Short-term preoperative treatment of primary hyperaldosteronism
After the diagnosis of hyperaldosteronism has been established by more definitive testing procedures, spironolactone may be administered at doses of 100 mg to 400 mg daily in preparation of surgery. For patients who are considered unsuitable candidates for surgery, Aldactone may be employed for long-term maintenance therapy at the lowest effective dosage determined for the individual patient.

Elderly
It is recommended that treatment is started with the lowest dose and titrated upwards as required to achieve maximum benefit. Care should be taken with severe hepatic and renal impairment which may alter drug metabolism and excretion.

Children
Initial dosage is 3 mg/kg body weight daily in divided doses. Dosage should be adjusted on the basis of response and tolerance. If necessary a suspension may be prepared by pulverizing spironolactone tablets with a few drops of glycerine and adding cherry syrup. Such a suspension is stable for one month when refrigerated at 2°C to 8°C.

4.3 Contraindications

Spironolactone is contraindicated in patients with the following:

- acute renal insufficiency, significant renal compromise, anuria;
- Addison's disease;
- hyperkalemia;
- hypersensitivity to spironolactone;
- concomitant use of eplerenone.

4.4 Special warnings and precautions for use

Concomitant use of spironolactone with other potassium-sparing diuretics, angiotensin-converting enzyme (ACE) inhibitors, non-steroidal anti-inflammatory drugs (NSAIDs), angiotensin II antagonists, aldosterone blockers, heparin, low molecular weight heparin or other drugs or conditions known to cause hyperkalemia, potassium supplements, a

diet rich in potassium, or salt substitutes containing potassium, may lead to severe hyperkalemia. Hyperkalemia can cause cardiac irregularities which may be fatal. Should hyperkalemia develop, spironolactone should be discontinued, and if necessary, active measures taken to reduce the serum potassium to normal.

Periodic estimation of serum electrolytes is recommended due to the possibility of hyperkalemia, hyponatremia and possible transient blood urea nitrogen (BUN) elevation, especially in the elderly and/or in patients with pre-existing impaired renal or hepatic function. Hyponatremia may be induced especially if spironolactone is administered in combination with other diuretics.

Reversible hyperchloremic metabolic acidosis, usually in association with hyperkalemia, has been reported to occur in some patients with decompensated hepatic cirrhosis, even in the presence of normal renal function.

Somnolence and dizziness have been reported in some patients. Caution is advised when driving or operating machinery until the response to initial treatment has been determined.

4.5 Interactions with other medicinal products and other forms of interaction

Concomitant use of drugs known to cause hyperkalemia with spironolactone may result in severe hyperkalemia.

Spironolactone may have an additive effect when given concomitantly with other diuretics and antihypertensive agents. The dose of such drugs may need to be reduced when spironolactone is added to the treatment regimen.

Spironolactone reduces vascular responsiveness to noradrenaline. Caution should be exercised in the management of patients subjected to regional or general anesthesia while they are being treated with spironolactone.

Spironolactone has been reported to increase serum digoxin concentration and to interfere with certain serum digoxin assays. In patients receiving digoxin and spironolactone the digoxin response should be monitored by means other than serum digoxin concentrations, unless the digoxin assay used has been proven not to be affected by spironolactone therapy. If it proves necessary to adjust the dose of digoxin, patients should be carefully monitored for evidence of enhanced or reduced digoxin effect.

NSAIDs such as aspirin, indomethacin, and mefenamic acid may attenuate the natriuretic efficacy of diuretics due to inhibition of intrarenal synthesis of prostaglandins and have been shown to reduce the diuretic effect of spironolactone. Combination of NSAIDs with potassium-sparing diuretics has been associated with severe hyperkalemia.

Spironolactone enhances the metabolism of antipyrine.

Hyperkalemic metabolic acidosis has been reported in patients given spironolactone concurrently with ammonium chloride or cholestyramine.

Co-administration of spironolactone with carbenoxolone may result in decreased efficacy of either agent.

Spironolactone binds to the androgen receptor and may increase prostate-specific antigen (PSA) levels in abiraterone-treated prostate cancer patients. Use with abiraterone is not recommended.

Spironolactone may reduce mitotane plasma levels in adrenocortical carcinoma patients and should not be used concomitantly with mitotane.

Like other diuretics, spironolactone reduces the renal clearance of lithium, thus increasing the risk of lithium toxicity. Monitor lithium levels periodically when spironolactone is co-administered.

4.6 Fertility, pregnancy and lactation

Spironolactone was devoid of teratogenic effects in mice. Rabbits receiving spironolactone showed reduced conception rate, increased resorption rate, and lower number of live births. No embryotoxic effects were seen in rats administered high dosages, but limited, dosage-related hypoprolactinemia and decreased ventral prostate and seminal vesicle weights in males and increased luteinizing hormone secretion and ovarian and uterine weights in females were reported. Feminization of the external genitalia of male fetuses was reported in another study in rats.

There are no studies in pregnant women. Spironolactone should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Canrenone, a major (and active) metabolite of spironolactone, appears in human breast milk. Because many drugs are excreted in human milk and because of the unknown potential for adverse effects on the breast-feeding infant, a decision should be made whether to discontinue breast-feeding or discontinue the drug, taking into account the importance of the drug to the mother.

4.7 Effects on ability to drive and use machines

See section **4.4 Special warnings and precautions for use**.

4.8 Undesirable effects

The following adverse events have been reported in association with spironolactone therapy:

Table 1. Adverse Drug Reactions	
System Organ Class	**Adverse Drug Reactions**
Neoplasms benign, malignant and unspecified (including cysts and polyps)	Benign breast neoplasm (male)
Blood and lymphatic system disorders	Agranulocytosis, Leukopenia, Thrombocytopenia
Metabolism and nutrition disorders	Hyperkalemia, Electrolyte imbalance
Psychiatric disorders	Confusional state, Libido disorder
Nervous system disorders	Dizziness, Headache, Ataxia
Gastrointestinal disorders	Nausea, Gastrointestinal disorder

Table 1. Adverse Drug Reactions	
System Organ Class	**Adverse Drug Reactions**
Hepatobiliary disorders	Hepatic function abnormal
Skin and subcutaneous tissue disorders	Pruritus, Rash, Urticaria, Toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), Drug reaction with eosinophilia and systemic symptoms (DRESS), Alopecia, Hypertrichosis
Musculoskeletal and connective tissue disorders	Muscle spasms
Renal and urinary disorders	Acute kidney injury
Reproductive system and breast disorders	Gynecomastia, Breast pain (male), Menstrual disorder, Breast pain (female)
General disorders and administration site conditions	Malaise

4.9 Overdose

Acute overdose may be manifested by nausea, vomiting, drowsiness, mental confusion, maculopapular or erythematous rash, or diarrhea. Hyponatremia or hyperkalemia may be induced but these effects are unlikely to be associated with acute overdosage. Symptoms of hyperkalemia may manifest as paresthesia, weakness, flaccid paralysis or muscle spasm and may be difficult to distinguish clinically from hypokalemia. Electrocardiographic changes are the earliest specific signs of potassium disturbances. No specific antidote has been identified. Improvement may be expected after withdrawal of the drug. General supportive measures including replacement of fluids and electrolytes may be indicated. For hyperkalemia, reduce potassium intake, administer potassium-excreting diuretics, intravenous glucose with regular insulin, or oral ion-exchange resins.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action
Spironolactone is a specific pharmacologic antagonist of aldosterone, acting primarily through competitive binding of receptors at the aldosterone-dependent sodium-potassium exchange site in the distal convoluted renal tubule. Spironolactone causes increased amounts of sodium and water to be excreted, while potassium is retained. Spironolactone acts both as a diuretic and as an antihypertensive drug by this mechanism. It may be given alone or with other diuretic agents that act more proximally in the renal tubule.

Aldosterone antagonist activity
Increased levels of the mineralocorticoid, aldosterone, are present in primary and secondary hyperaldosteronism. Edematous states in which secondary aldosteronism is usually involved include congestive heart failure, hepatic cirrhosis, and the nephrotic syndrome. By competing with aldosterone for receptor sites, spironolactone provides effective therapy for edema and ascites in those conditions. Spironolactone counteracts secondary aldosteronism induced by the volume depletion and associated sodium loss caused by active diuretic therapy.

Spironolactone is effective in lowering the systolic and diastolic blood pressure in patients with primary hyperaldosteronism. It is also effective in most cases of essential hypertension, despite the fact that aldosterone secretion may be within normal limits in benign essential hypertension.

Spironolactone has not been demonstrated to elevate serum uric acid, to precipitate gout, or to alter carbohydrate metabolism.

5.2 Pharmacokinetic properties

Spironolactone is rapidly and extensively metabolized. Sulfur-containing products are the predominant metabolites and are thought to be primarily responsible, together with spironolactone, for the therapeutic effects of the drug. The following pharmacokinetic data were obtained from 12 healthy volunteers following the administration of 100 mg of spironolactone daily for 15 days. On the 15th day, spironolactone was given immediately after a low-fat breakfast and blood was drawn thereafter.

	Accumulation Factor: AUC (0-24 hours, Day 15)/AUC (0-24 hours, Day 1)	**Mean Peak Serum Concentration**	**Mean (SD) Post-steady-state Half-life**
7-α-(thiomethyl) spirolactone	1.25	391 ng/mL at 3.2 hours	13.8 hours (6.4) (terminal)
6-β-hydroxy-7-α-(thiomethyl) spirolactone	1.50	125 ng/mL at 5.1 hours	15.0 hours (4.0) (terminal)
Canrenone	1.41	181 ng/mL at 4.3 hours	16.5 hours (6.3) (terminal)
Spironolactone	1.30	80 ng/mL at 2.6 hours	Approximately 1.4 hours (0.5) (β half-life)

The pharmacological activity of spironolactone metabolites in man is not known. However, in adrenalectomized rats, the antimineralocorticoid activities of the metabolites canrenone (C), 7-α-(thiomethyl) spirolactone (TMS), and 6-β-hydroxy-7-α-(thiomethyl) spirolactone (HTMS), relative to spironolactone, were 1.10, 1.28, and 0.32, respectively. Relative to spironolactone, their binding affinities to the aldosterone receptors in rat kidney slices were 0.19, 0.86, and 0.06, respectively.

In humans, the potencies of TMS and 7-α-thiospirolactone in reversing the effects of the synthetic mineralocorticoid, fludrocortisone, on urinary electrolyte composition were 0.33 and 0.26, respectively, relative to spironolactone. However, since the serum concentrations of these steroids were not determined, their incomplete absorption and/or first-pass metabolism could not be ruled out as a reason for their reduced *in vivo* activities.

Spironolactone and its metabolites are more than 90% bound to plasma proteins. The metabolites are excreted primarily in the urine and secondarily in bile.

The effect of food on spironolactone absorption was assessed in a single-dose study of nine healthy, drug-free volunteers. Food increased the bioavailability of unmetabolized spironolactone by almost 100%. The clinical importance of this finding is not known.

5.3 Preclinical safety data

Carcinogenesis, mutagenesis, impairment of fertility

Orally administered spironolactone has been shown to be a tumorigen in dietary administration studies performed in rats, with its proliferative effects manifested on endocrine organs and the liver. In an 18-month study using doses of about 50, 150 and 500 mg/kg/day, there were statistically significant increases in benign adenomas of the thyroid and testes and, in male rats, a dose-related increase in proliferative changes in the liver (including hepatocytomegaly and hyperplastic nodules). In 24-month studies in which rats were administered doses of about 10, 30, 100, and 150 mg/kg/day of spironolactone, the range of proliferative effects included significant increases in hepatocellular adenomas and testicular interstitial cell tumors in males, and significant increases in thyroid follicular cell adenomas and carcinomas in both sexes. There was also a statistically significant increase in benign uterine endometrial stromal polyps in females.

A dose-related (above 30 mg/kg/day) incidence of myelocytic leukemia was observed in rats fed daily doses of potassium canrenoate (a compound chemically similar to spironolactone and whose primary metabolite, canrenone, is also a major product of spironolactone in man) for a period of 1 year. In 2-year studies in the rats, oral administration of potassium canrenoate was associated with myelocytic leukemia and hepatic, thyroid, testicular and mammary tumors.

Neither spironolactone nor potassium canrenoate produced mutagenic effects in tests using bacteria or yeast. In the absence of metabolic activation, neither spironolactone nor potassium canrenoate has been shown to be mutagenic in mammalian tests *in vitro.* In the presence of metabolic activation, spironolactone has been reported to be negative in some mammalian mutagenicity tests *in vitro* and inconclusive (but slightly positive) for mutagenicity in other mammalian tests *in vitro.* In the presence of metabolic activation, potassium canrenoate has been reported to test positive for mutagenicity in some mammalian tests *in vitro,* inconclusive in others, and negative in still others.

In a three-litter reproduction study in which female rats received dietary doses of 15 and 50 mg/kg/day of spironolactone, there were no effects on mating and fertility, but there was a small increase in incidence of stillborn pups at 50 mg/kg/day. When injected into female rats (100 mg/kg/day for 7 days, i.p.), spironolactone was found to increase the length of the estrous cycle by prolonging diestrus during treatment and inducing constant diestrus during a 2-week post-treatment observation period. These effects were associated with retarded ovarian follicle development and a reduction in circulating estrogen levels, which would be expected to impair mating, fertility and fecundity. Spironolactone (100 mg/kg/day), administered i.p. to female mice during a 2-week cohabitation period with untreated males, decreased the number of mated mice that conceived (effect shown to be caused by an inhibition of ovulation) and decreased the number of implanted embryos in those that became pregnant (effect shown to be caused by an inhibition of implantation), and at 200 mg/kg also increased the latency period to mating.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aldactone 25 mg contains: Calcium sulphate dehydrate, maize starch, polyvinyl pyrrolidone, magnesium stearate, peppermint flavor, hypromellose, polyethylene glycol and opaspray yellow (contains E171 and E172).

6.2 Incompatibilities

None stated.

6.3 Shelf-life

Refer to shelf-life statement on outer carton.

6.4 Special precautions for storage

Store in a dry place below 30°C.

6.5 Nature and contents of container

Aldactone 25 mg tablet is packed in PVC/foil blister packs containing 100 tablets.

6.6 Special precautions for disposal and other handling

None.

7. PRODUCT OWNER

Pfizer Inc
New York,
United States

ALD-SIN-0225/1
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Package leaflet: Information for the patient

Aldactone® 25mg 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:
- 'Ascites' - too much fluid in your abdomen and 'edema' - 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
- 'Nephrotic syndrome' - a kidney disorder that causes too much fluid in your body
- '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.

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 have severe kidney disease
- you cannot pass urine
- you have Addison's disease; (a hormone deficiency characterized by extreme weakness, loss of weight and low blood pressure)
- you have hyperkalemia (raised blood potassium levels)
- you are taking eplerenone (a medicine for high blood pressure).

Warnings and precautions
Talk to your doctor or pharmacist before taking Aldactone if:
- you have kidney or liver problems. Your doctor will routinely assess you particularly if you are elderly.
- you have a disease that can result in electrolyte balance disturbance in your blood such as potassium or sodium

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 hyperkalemia (increased potassium blood level). The symptoms of severe hyperkalemia might include muscle cramps, irregular heart rhythm, diarrhea, 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. Your doctor may wish to alter your dose of Aldactone if you are taking any of the following:

- other diuretics
- medicines for high blood pressure including angiotensin-converting enzyme (ACE) inhibitors, angiotensin II antagonists, aldosterone blockers
- digoxin (medicine for heart failure)
- non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin, indomethacin, mefenamic acid, antipyrine
- ammonium chloride
- cholestyramine (medicine used to lower cholesterol)
- carbenoxolone (medicine used for ulcers)
- heparin or low molecular weight heparin (medicines used to prevent blood clots)
- potassium supplements
- medicines known to cause hyperkalemia (raised blood potassium levels)
- lithium.

Aldactone reduces your responsiveness to noradrenaline. If you are going to have an operation where you will be given an anesthetic, 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 tumors of the adrenal glands. This medicine should not be used together with mitotane.

Aldactone with food, drink and alcohol
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 is no data on the use of Aldactone in pregnant women. Your doctor will only prescribe Aldactone if the potential benefit outweighs the potential risk.

Breast-feeding
Aldactone may be present in human breast milk. You should discuss the use of Aldactone with your doctor, who will advise you whether to consider discontinue breast-feeding or discontinue 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 number of tablets you need to take depends on your illness.

Recommended dose
This medicine should be taken once a day with food.

Adults
The adult dose varies from 100 mg to 400 mg 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.

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 needed, you can make a liquid form by crushing the Aldactone tablets, mixing them with a few drops of glycerine and adding cherry syrup. This liquid can be kept in the fridge at 2°C to 8°C for one month.

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 diarrhea 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.

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.

- Detachment of the top layer of skin from the lower layers of skin, all over the body (toxic epidermal necrolysis – TEN)
- 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)
- Skin rash, fever and swelling (which could be symptoms of something more serious, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- 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.

List of other side effects of Aldactone:

- Changes in the breast such as breast lumps (in men)
- 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
- Raised potassium in the blood

- Disturbances in body electrolytes
- Confusion
- Change in sex drive for both men and women
- Dizziness
- Headache
- Inability to coordinate muscle movements
- Vomiting or feeling sick
- Digestion problems, stomach upset
- Abnormal functioning of the liver
- Itching of the skin
- Rash
- Skin allergy with development of itchiness and hives, nettle like rash
- Hair loss
- Excessive hair growth
- Muscle or leg cramps
- Kidney failure or abnormal function
- Breast enlargement
- Breast pain (in men)
- Menstrual problems in women
- Breast pain (in women)
- Feeling generally unwell

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.

Store in a dry place below 30°C.

Do not use this medicine after the expiry date which is stated on the blister or carton 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 25 mg tablet contains 25 mg of spironolactone.

The other ingredients are calcium sulphate dehydrate, maize starch, polyvinyl pyrrolidone, magnesium stearate, peppermint flavor, hypromellose, polyethylene glycol and opaspray yellow (contains E171 and E172).

What Aldactone looks like and contents of the pack
Aldactone 25 mg tablets come in PVC/foil blister packs containing 100 tablets.

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