ALDACTONE 100 mg Tablet

For oral use

Sold by prescription | Diuretic | Spironolactone

ACTIVE INGREDIENT

Each tablet contains 100 mg spironolactone.

EXCIPIENTS

Calcium sulfate dihydrate, Corn starch, PVP K-30, Magnesium stearate, Felcofix peppermint (peppermint flavor)

PHARMACEUTICAL FORM

White, round, peppermint-scented tablets with "SEARLE" on one side, in blister packs containing 16 tablets.

Read this PATIENT INFORMATION LEAFLET carefully before you start using this medicine, because it contains important information for you.

- Keep this leaflet. You may want to read it again later.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally, do not give it to others.
- During the use of this medicine, when you go to a doctor or hospital, tell your doctor that you are using this medicine.
- Follow the instructions in this leaflet exactly. Do not use high or low doses other than the dose recommended for you.

IN THIS PATIENT INFORMATION LEAFLET

1.What is ALDACTONE and what is it used for?

2.Things to consider before using ALDACTONE

3.How to use ALDACTONE?

4.What are the possible side effects?

5.How to store ALDACTONE?

What is ALDACTONE and what is it used for?

ALDACTONE belongs to the group of medicines called diuretics, which are used to increase urine output. ALDACTONE is available as white, round, peppermint-scented tablets with "SEARLE" on one side, in blister packs containing 16 tablets.

If you have swelling in your ankles or are short of breath, see a doctor. This may be due to a weakening of your heart's pumping power when there is too much fluid in your body. This condition is called congestive heart failure. Circulating extra fluid in your body means your heart has to work harder. Your doctor will prescribe ALDACTONE to help remove excess fluid from your body. When you take ALDACTONE, you will need to go to the toilet more often. In this way, you will excrete the excess fluid with your urine.

ALDACTONE is also used to treat the following conditions:

Essential hypertension (hypertension of unknown cause)

Nephrotic syndrome (a kidney disease that causes too much fluid to accumulate in the body)

Ascites (e.g., fluid accumulation in the abdomen caused by liver cirrhosis)

Primary aldosteronism (fluid accumulation in the body due to very high levels of the hormone aldosterone)

Combined treatment of hypokalemia/hypomagnesemia with diuretics (blood potassium level falling below normal)

Treatment of hirsutism (increased hair growth)

Things to consider before using ALDACTONE

DO NOT USE ALDACTONE in the following situations:

If you have;

Hypersensitivity to spironolactone or any of the excipients,

Addison's disease (a condition where the adrenal glands do not function properly),

Had an unusual or allergic reaction to spironolactone in the past,

Hyperkalemia (increased potassium level in the blood),

Are unable to urinate,

Have severe kidney disease,

Are breastfeeding,

Are using eplerenone (used for chronic heart failure),

Are using potassium-sparing diuretic tablets or potassium supplement tablets,

Children with moderate to severe kidney disease should not use ALDACTONE.

USE ALDACTONE CAREFULLY in the following situations:

If you have;

Severe kidney disease; especially in children with liver disease or hypertension, tell your doctor about this condition. Especially if you are in the elderly group, your doctor may ask for routine evaluation.

Are pregnant,

Have difficulty urinating,

Have severe heart failure,

Have a disease that causes an imbalance of electrolytes such as sodium and potassium in your blood,

Be careful if you are using ALDACTONE together with other diuretic tablets that may cause a decrease in blood sodium levels (hyponatremia).

If you have reduced kidney function or kidney failure, severe increases in your blood potassium levels may occur. This can affect your heart function and, in very extreme cases, can be fatal.

The use of potassium-rich foods and some medications such as potassium supplements together with ALDACTONE can cause severe hyperkalemia (increased potassium in the blood). Symptoms of severe hyperkalemia may include muscle cramps, irregular heartbeat, diarrhea, nausea, dizziness, and headache.

Using ALDACTONE with food and drink

ALDACTONE should be taken with food. It should not be used with alcohol.

Pregnancy

> Consult your doctor or pharmacist before using the medicine.
>
> If you are pregnant, think you may be pregnant, or are planning to become pregnant, tell your doctor. You may use ALDACTONE if your doctor deems it necessary.
>
> If you realize you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breastfeeding

> Consult your doctor or pharmacist before using the medicine.
>
> Do not use ALDACTONE if you are breastfeeding.
>
> If you are breastfeeding and need to use ALDACTONE, consult your doctor to determine an alternative method of infant feeding.

Driving and using machines

Drowsiness and dizziness have been reported in some patients receiving ALDACTONE treatment. Therefore, ALDACTONE may affect the ability to drive and use machines. Caution should be exercised when driving or operating machinery.

Important information about some of the excipients in ALDACTONE

No adverse effects are expected from the excipients in ALDACTONE unless you have an excessive sensitivity to them.

Does not contain any excipients requiring warning.

Using with other medicines

If you are going to have an operation with anesthesia, tell your doctor that you are using ALDACTONE.

Your doctor may need to adjust your ALDACTONE dose if you are taking any of the following medicines:

- Digoxin, used in the treatment of heart disease, or carbenoxolone, used for digestive system disorders,
- Medicines used for the treatment of high blood pressure (ACE inhibitors),
- Other medicines used as diuretics (such as potassium-sparing diuretics),
- Non-steroidal anti-inflammatory drugs (NSAIDs) such as acetylsalicylic acid, indomethacin, mefenamic acid, or ibuprofen, used as anti-inflammatory agents,
- Potassium supplements
- Heparin or low molecular weight heparin used to prevent blood clotting
- Antipyrine used as a pain reliever and fever reducer
- Medicines known to cause hyperkalemia (high potassium levels in the blood)

Trimethoprim and trimethoprim-sulfamethoxazole used as anti-infectives

Lithium, used in the treatment of mood disorders,

Tubocurarine, used for muscle relaxation during diagnosis of certain diseases and surgical/non-surgical procedures,

Corticosteroids used for anti-inflammatory and immunomodulatory purposes,

Alcohol, barbiturates, narcotics, which may cause a decrease in blood pressure when used together.

ALDACTONE reduces the body's response to noradrenaline. If you are going to have surgery that requires anesthesia, tell your doctor about this.

Tell your doctor if you are using abiraterone for prostate cancer treatment.

If you are currently using or have recently used any prescription or over-the-counter medicine, please inform your doctor or pharmacist about them.

How to use ALDACTONE?

Instructions for proper use and dose/frequency of administration:

Unless your doctor or pharmacist advises otherwise, follow these instructions.

Your doctor will decide how much ALDACTONE you need. This amount varies, and your doctor will adjust the appropriate dose for you. For adults, it can be given as a single daily dose or in divided doses. It should be taken with meals.

The adult dose can vary between 25 and 200 mg of spironolactone per day. If you are unsure how much to take, consult your doctor or pharmacist.

Route and method of administration:

ALDACTONE is taken orally.

Different age groups:

Use in children:

If you are giving this medicine to children, the number of tablets to be given depends on the child's weight. Your doctor will inform you about the number of tablets to be given.

Use in the elderly:

Your doctor will start your treatment with a low dose and gradually increase your dose until the desired effect is achieved.

Special use cases:

Kidney failure:

Should not be used in acute kidney failure, deterioration of kidney function, or severe kidney dysfunction.

Liver failure:

Caution should be exercised in severe liver failure that may alter drug metabolism and excretion.

If you have the impression that the effect of ALDACTONE is too strong or too weak, talk to your doctor or pharmacist.

If you use more ALDACTONE than you should:

If you have used more ALDACTONE than you should, talk to a doctor or pharmacist.

Symptoms of overdose include feeling sleepy, dizzy, thirsty, tired, and you may feel confused. You may have diarrhea or skin rashes in the form of small bumps or widespread flat red areas on the skin. Changes in blood sodium and potassium levels may cause you to feel tired and you may experience tingling, pain, stinging, numbness, and/or muscle spasms in your skin. However, these symptoms are not necessarily associated with severe overdose.

If you forget to use ALDACTONE

If you forget to take your medicine, 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 forgotten doses.

Effects that may occur when treatment with ALDACTONE is stopped

Continue taking the medicine until your doctor tells you to stop, even if you feel well.

If you stop using the medicine before the prescribed time, your condition may worsen. If you have any questions about the use of the medicine, consult your doctor.

What are the possible side effects?

Like all medicines, side effects may occur in people sensitive to the ingredients in ALDACTONE.

Side effects are listed as follows in the categories shown:

Very common: May be seen in at least 1 in 10 patients.

Common: May be seen in less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon: May be seen in less than 1 in 100 patients, but more than 1 in 1,000 patients.

Rare: May be seen in less than 1 in 1,000 patients.

Very Rare: May be seen in less than 1 in 10,000 patients, but more than 1 in 10,000 patients.

Unknown: Cannot be estimated from the available data.

If any of the following occur, stop using ALDACTONE and immediately inform your doctor or go to the emergency department of the nearest hospital:

Unknown:

Itching and hives on the lips and other parts of the body (Stevens-Johnson syndrome)

Separation of the upper layers of the skin from the lower layers throughout the body (toxic epidermal necrolysis)

Skin rash, fever, and edema (May be signs of a more serious condition, drug rash, eosinophilia, and systemic symptoms)

Yellow skin and eyes (jaundice), ALDACTONE may cause liver dysfunction.

Irregular heartbeat (potentially fatal), tingling sensation, loss of muscle function (paralysis) or difficulty breathing; these may be signs of elevated potassium levels in the blood. Your doctor will order regular blood tests to monitor potassium and other electrolyte levels. If deemed necessary, your treatment may be terminated.

These are all very serious side effects. If you experience any of these, you may need urgent medical intervention or hospitalization.

If you notice any of the following, tell your doctor:

Unknown:

- Nausea, upset stomach,
- Drowsiness, dizziness,
- Menstrual problems in women,
- Changes in sexual desire (libido) in women and men,
- Electrolyte imbalance in the body (high calcium in the blood)
- Decrease in the number of infection-fighting cells (leukopenia); decrease in the number of blood cells that enable blood clotting (thrombocytopenia),
- Breast enlargement in men (gynecomastia); this condition resolves when treatment is stopped; breast lumps, breast pain,
- Deepening of the voice in women,
- Skin redness, general itching,
- Allergy with the development of hives and itching on the skin; excessive hair growth (hypertrichosis),
- Hair loss,
- General fatigue, muscle and leg cramps
- Acute kidney failure or abnormal liver functions
- Increased potassium levels in the blood (hyperkalemia)
- Pemphigoid (a skin disease characterized by fluid-filled blisters on the skin, crusting and superficial wound formation after the blisters burst)

These are mild side effects of ALDACTONE.

Reporting of side effects

If you experience any side effects, whether or not listed in this Patient Information Leaflet, talk to your doctor, pharmacist, or nurse. You can also report side effects to the Turkish Pharmacovigilance Center (TÜFAM) by clicking on the "Drug Side Effect Notification" icon on www.titck.gov.tr or by calling the side effect notification line at 0 800 314 00 08. By reporting side effects, you will contribute to obtaining more information about the safety of the medicine you are using.

How to store ALDACTONE?

Keep ALDACTONE out of the sight and reach of children and in its original packaging.

Store below 30°C at room temperature.

Store in its original packaging.

Use in accordance with the expiry date

Do not use ALDACTONE after the expiry date on the packaging.

Do not throw away expired or unused medicines! Hand them over to the collection system determined by the Ministry of Environment and Urbanization.

Marketing Authorisation Holder

ALİ RAİF İLAÇ SAN. A.Ş.
Kağıthane/İSTANBUL

Manufacturer

ALİ RAİF İLAÇ SAN. A.Ş.
Başakşehir/İSTANBUL

This patient information leaflet was approved on [Date].