

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

**Aldactone® 25 mg
Film-coated tablets**

The active ingredient and its quantity:

Each film-coated tablet contains:

spironolactone 25 mg

For a list of inactive ingredients and allergens, see section 6 "Further Information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

- To treat congestive heart failure.
- To treat cirrhosis with edema and ascites.

Therapeutic group:

Spironolactone belongs to a group of medicines called potassium-sparing diuretics.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient or to any of the other ingredients in the medicine (listed in section 6).
- you suffer from urinary retention.
- you suffer from severe kidney disease.
- you suffer from Addison's disease (a disease characterized by a feeling of exhaustion, loss of weight and by low blood pressure).
- you suffer from hyperkalaemia (excessive blood potassium).
- you are breastfeeding.
- you are taking potassium-sparing diuretics or potassium supplements.
- you are taking a medicine that contains the active ingredient eplerenone (administered to treat heart failure).
- Do not use the medicine in children suffering from moderate to severe kidney disease.

Special warnings regarding use of the medicine

Before treatment with Aldactone, tell your doctor if:

- you suffer from kidney disease, especially children with hypertension or liver disease. The doctor will routinely assess you, particularly if you are elderly.
- you have difficulty passing urine.
- you have a disease that can result in electrolyte balance disturbance in your blood such as potassium or sodium.
- you have severe heart failure.

- you are pregnant.
- If you experience reduced kidney function or kidney failure, you may have a severe increase in the levels of potassium in the blood. This condition may affect the way the heart functions and in extreme cases may even be fatal.
- Concomitant use 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.

Drug interactions

If you are taking or have recently taken, other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist. Your doctor may want to adjust the Aldactone dosage. Particularly if you are taking:

- digoxin or carbenoxolone
- medicines for high blood pressure including preparations from the angiotensin-converting enzyme (ACE) inhibitor group
- diuretics
- non-steroidal anti-inflammatory drugs (NSAIDs) (such as aspirin, indomethacin, mefenamic acid or ibuprofen)
- potassium supplements
- heparin or low molecular weight heparin (medicines to prevent blood clots)
- antipyrine
- medicines known to cause hyperkalaemia (raised blood potassium levels)
- trimethoprim and trimethoprim-sulfamethoxazole

Aldactone reduces your responsiveness to noradrenaline. If you are going to have an operation where you are expected to receive anaesthetics, tell the doctor that you are taking Aldactone

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

Tell your doctor if you are being treated with mitotane for malignant tumors of the adrenal glands. Do not use this medicine together with mitotane.

Use this medicine and food

Take the medicine with food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, consult your doctor before taking this medicine.

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

Do not use the medicine when you are breastfeeding.

Consult with the doctor regarding use of the medicine. The doctor will advise you to consider an alternative method of feeding your baby while you are taking this medicine.

Driving and using machines

Take care when driving a car or operating dangerous machinery. Use of this medicine may cause drowsiness and dizziness which may affect your ability to drive a car or operate dangerous machinery.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine. The dosage and treatment regimen will be determined by your doctor only.

The medicine should be taken once a day with food.

Elderly

The doctor may prescribe a low dosage for you and gradually increase the dosage as needed, to obtain the desired effect.

Children and adolescents

Dosages for children are calculated according to their weight.

The attending doctor will calculate the dose that the child should be given.

The treatment in children should be done under the supervision of a specialist in treating children.

Do not exceed the recommended dose!

Always take the regimen recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

There is no information regarding crushing/halving/chewing.

If you took an overdose or if a child has accidentally swallowed some medicine, immediately refer to a doctor or go to a hospital emergency room and bring the medicine package with you. The symptoms of an overdose may include feeling drowsy, dizzy, feeling dehydrated and you may feel confused. You may suffer from nausea or vomiting, diarrhoea and rashes that will appear as flat red areas of skin with overlapping small raised bumps.

Changes in the blood sodium and potassium levels may cause a feeling of weakness, tingling, or numbness of the skin and/or muscle spasms, but these symptoms are unlikely when an overdose is taken.

If you forget to take this medicine at the required time, take a dose as soon as you remember unless it is almost time for the next dose, but never take a double dose to compensate for a forgotten dose!

If you stop taking this medicine

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 medicine too soon, your condition may get worse.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Aldactone may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Refer to the doctor immediately if you experience any of the following symptoms after taking the medicine. Although these effects are rare, the symptoms may 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 the skin, all over the body (toxic epidermal necrolysis)
- Skin rash, fever and swelling (which could be symptoms of something more serious – Drug Reaction with Eosinophilia and Systemic Symptoms).
- Yellow tint to the skin and eyes (jaundice)
- The medicine can impair liver function
- Irregular heartbeat which can be fatal, tingling sensation, paralysis (inability to use muscles) or difficulty in breathing, which may be symptoms of raised potassium levels in the blood. The doctor will conduct periodic blood tests to monitor potassium and other electrolyte levels in the blood. The doctor may stop the treatment.

Additional side effects:

Very common side effects (may affect more than 1 in 10 people):

- Raised potassium levels in the blood

Common side effects (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 kidney function
- Breast tissue enlargement in men
- Breast pain (in men)
- Feeling generally unwell

Uncommon side effects (may affect up to 1 in 100 people):

- Changes in the breast such as: breast lumps
- Changes in electrolyte levels in the body, such as: high blood calcium levels
- Abnormal functioning of the liver
- Allergic reaction in the skin, including itchiness and hives, nettle like rash (urticaria)
- Menstrual changes in women
- Breast pain (in women)

Side effects of unknown frequency (effects whose frequency cannot be determined from the available data):

- Lowered white blood cell count in blood
- Reduced number of cells in the blood that fight infections, white blood cells, which makes infection more likely
- Reduced number of cells that help with blood clotting, which increases the risk of bleeding or bruising
- Changes in sex drive (in both men and women)
- Digestive problems, abdominal discomfort

- Skin problem presenting with fluid-filled blisters (pemphigoid)
- Hair loss
- Excessive hair growth

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

- Store the medicine at a temperature below 30°C.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

Calcium sulphate dihydrate, corn starch, povidone K-30, peppermint flavor, hypromellose 5cps, hypromellose 15cps, opaspray M-1-6032B yellow, magnesium stearate, polyethylene glycol 400.

What the medicine looks like and the contents of the pack:

A carton package that contains two trays (blisters).

Each tray contains 10 round tablets.

Registration holder's name and address: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 125.97.24826

Revised in 04/2025.