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
The list of inactive and allergenic ingredients in the preparation is in section 6.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the 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.

1. WHAT IS THE MEDICINE INTENDED FOR?
- To treat 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 THE MEDICINE
X Do not use the medicine if:

x you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine (as detailed in section 6).
x you suffer from urinary retention.
x you suffer from severe kidney disease.
x you suffer from Addison's disease (a disease characterized by a feeling of exhaustion, loss of weight and by low blood pressure).
x you suffer from hyperkalemia (excessive blood potassium).
x you are breastfeeding.
x you are taking potassium-sparing diuretics or potassium supplements.
x you are taking a medicine that contains the active ingredient eplerenone (administered to treat heart failure).
x 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 the 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 hyperkalemia might include muscle cramps, irregular heart rhythm, diarrhea, nausea, dizziness or headache.

! Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Your doctor may want to adjust the Aldactone® dosage. Especially 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 hyperkalemia (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 anesthetics, tell the doctor that you are taking Aldactone®.

! Use of the medicine and food
Take the medicine with food.

! Pregnancy and breastfeeding
If you are pregnant, breastfeeding, think you may be pregnant or are planning to become pregnant, consult the doctor before taking this medicine.
Do not use the medicine if 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 SHOULD YOU USE THE MEDICINE?
Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation. The dosage and treatment regimen will be determined by the 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!
Complete the treatment 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 the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine 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, diarrhea 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 the 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 further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS
As with any medicine, use of Aldactone® may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from 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 a side effects occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?
- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store the medicine at a temperature below 30°C.

6. FURTHER INFORMATION
In addition to the active ingredient, the 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 package:
A carton package that contains two trays (blisters).
Each tray contains 10 round tablets.

License holder: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Manufacturer: Piramal Healthcare Limited, Northumberland, UK.

This leaflet was checked and approved by the Ministry of Health in December 2016 and was updated in accordance with the Ministry of Health guidelines in August 2019

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