PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

Spironolactone Teva 25 mg
Tablets

Composition:
Each tablet contains:
Spironolactone 25 mg

Spironolactone Teva 100 mg
Tablets

Composition:
Each tablet contains:
Spironolactone 100 mg

For information about inactive ingredients see section 6 - "Additional information".

Read the entire leaflet carefully before using the medicine.
This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for your treatment. 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?

Treatment of congestive heart failure, cirrhosis of the liver accompanied by edema and ascites, lowering blood pressure, adrenal gland overactivity (hyperaldosteronism), hypokalemia (low levels of potassium in the blood).

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

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (see section 6 – "additional information").
- You suffer from urinary retention.
- You suffer from a severe kidney disease.
- You suffer from Addison's disease (a disease characterized by a feeling of exhaustion, loss of weight and low blood pressure).
- You suffer from hyperkalemia (excess potassium in the blood).
- 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 the use of the medicine
Before treatment with Spironolactone Teva, inform the doctor if:

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

If you experience deteriorating kidney function or kidney failure, you may suffer from a severe increase in the level of potassium in the blood. This condition may affect the heart function and in extreme cases may even be fatal.
Concomitant use of Spironolactone Teva with certain medicines, potassium supplements or food rich in potassium may lead to severe hyperkalemia (increased levels of potassium in the blood). The symptoms of severe hyperkalemia may include muscle spasm, irregular heart rhythm, diarrhea, nausea, dizziness or headache.

Drug-drug interactions
If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the doctor or the pharmacist. Your doctor may want to adjust the dosage of Spironolactone Teva. Especially if you are taking:

- Digoxin or carbenoxolone
- Medicines used to treat high blood pressure including preparations from the angiotensin-converting enzyme inhibitors group (ACE inhibitors)
- Diuretic medications
- Non-steroidal anti-inflammatory preparations (NSAIDs) (such as aspirin, indomethacin, mefenamic acid or ibuprofen)
- Potassium supplements
- Heparin or low molecular weight heparin (medicines to prevent blood clotting)
- Antipyrine
- Medicines that may cause hyperkalemia (high levels of potassium in the blood)
- Trimethoprim and trimethoprim-sulfamethoxazole

Spironolactone reduces your response to noradrenaline. If you are about to have an operation where you are expected to receive anesthetic medications, tell the doctor that you are taking Spironolactone Teva.
Tell the doctor if you are taking abiraterone for treatment of prostate cancer.

Use of the medicine and food
The medicine should be taken 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 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 operating machinery
You must be careful 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 how to use the preparation. The dosage and treatment regimen will be determined only by the doctor.
The medicine should be taken once a day with food.
The tablet can be halved at the score line.
There is no information regarding pulverization or chewing.

The elderly
The doctor is likely to prescribe a low dosage for you and will gradually increase the dosage as needed, in order to achieve the desired effect of the medicine.

Children and adolescents
Dosages for children are calculated according to their weight. The attending physician will calculate the dosage to be given to the child.
The treatment of children should be carried out under the supervision of a pediatric specialist.

Do not exceed the recommended dose!
You should complete the treatment recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting a doctor.
If you took an overdose or by mistake a child swallowed this medicine, go immediately to the doctor or the emergency room of the hospital and take the package of the medicine with you. The symptoms of an overdose may include a feeling of drowsiness, dizziness, a feeling of dehydration and you may feel confused. You may suffer from nausea or vomiting, diarrhea and rashes that will appear as red flat areas with overlapping small red bumps.
Changes in the levels of sodium and potassium in the blood may cause a feeling of weakness, tingling or numbness of the skin and / or muscle spasm, but these symptoms are uncommon when an overdose is taken.
If you forgot 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 by no means take a double dose to compensate for a forgotten dose!
Follow the treatment as recommended by the doctor.

If you stop taking the medicine
It is important to keep taking Spironolactone Teva 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 every time you take the medicine. Wear glasses if you need them.
If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Spironolactone Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.
Refer to the doctor immediately if you suffer from one of the following side effects after taking the medicine. Although these effects are rare, the symptoms may be severe:

- Itching and blistering of the skin around the lips and the rest of the body, red or purple spreading rash and the formation of blisters (Stevens-Johnson syndrome)
- Detachment of the top layer of the skin from the lower layers, all over the body (toxic epidermal necrolysis)
- Skin rash, fever and swelling (which may be symptoms of a more serious condition - Drug Reaction with Eosinophilia and Systemic Symptoms)
- Yellow tinge to the skin and eyes (jaundice)
- The medicine can impair liver function
- Irregular heartbeat which can be fatal, tingling sensation, paralysis (inability to use the muscles) or difficulty breathing which may be symptoms of high levels of potassium in the blood. The doctor will perform periodic blood tests to monitor the levels of potassium and other electrolytes in your blood. The doctor may stop the treatment.

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

- High levels of potassium in the blood

Common side effects (may affect up to 1 in 10 users):

- Confusion
- Dizziness
- Vomiting or nausea
- Itching of the skin
- Rash
- Muscle or leg cramps
- Kidney failure or impaired kidney function
- Breast tissue enlargement in men
- Breast pain (in men)
- Feeling generally unwell

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

- Changes in the breast, such as breast lumps
- Changes in the electrolyte levels in the body, such as high calcium levels in the blood
- Abnormal liver function
- An allergic skin reaction that includes itching and hives, reticulated rash (urticaria)
- Menstrual changes in women
- Breast pain (in women)

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

- Low white blood cell count
- Reduced number of cells in the blood that fight infections, white blood cells, which increases the likelihood of infections
- Reduced number of cells that help with blood clotting, which increases the likelihood of bleeding or bruising
- Changes in libido (in men and in women)
- Digestive problems, abdominal discomfort
- Skin problem manifested by fluid -filled blisters (pemphigoid)
- Hair loss
- Excessive hairiness

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.
Reporting side effects
Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
Store in a dry place under 25°C.

6. Additional information

In addition to the active ingredient, the medicine also contains:
Calcium sulfate, starch, povidone, felcofix peppermint, magnesium stearate.
Spironolactone Teva 25 mg tablets also contains:
Color red FD&C No.3 Lake 15% (E127).
What does the medicine look like and what are the contents of the package:
Spironolactone Teva 25 mg: A pink, round, flat tablet with beveled edges, on one side of the tablet there is a score line and the other side is debossed with "TEVA". The tablet has a mint scent. Marketed in a blister pack containing 20 or 30 tablets.
Spironolactone Teva 100 mg: A white, round, flat tablet with beveled edges, on one side of the tablet there is a score line and the other side is debossed with "TEVA". The tablet has a mint scent. Marketed in a blister pack containing 20, 30 or 100 tablets.
Not all package sizes may be marketed.
Name and address of the manufacturer and marketing authorization holder:
Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.
The leaflet was revised in June 2022 in accordance with the Ministry of Health guidelines.
Registration numbers of the medicine in the national drug registry of the Ministry of Health:
Spironolactone Teva 25 mg: 026.51.21060
Spironolactone Teva 100 mg: 030.32.21061

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