Package leaflet: Information for the user

Spironolactone 25 mg film-coated tablets
Spironolactone 50 mg film-coated tablets
Spironolactone 100 mg film-coated tablets
spironolactone

Read all of this leaflet carefully before you start using 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 iftheir signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Spironolactone film-coated tablet is and what it is used for

The active ingredient of the tablets is Spironolactone. Spironolactone belongs to a particular group of medicines, known as aldosterone antagonists, which inhibit the action of the hormone aldosterone. One of the functions of aldosterone is to ensure that the body retains sodium. It forms part of a system that regulates the balance of fluids and salts in the body ('RAAS', renin angiotensin aldosterone system). Spironolactone promotes the excretion of urine in patients in whom there is an accumulation of fluid in the tissues (oedema) or in the abdominal cavity (ascites) by increasing the amount of sodium (salt) excreted in the urine. Potassium loss as a possible consequence of using certain diuretics is reduced. The antihypertensive effect relies on the excretion of water and salt.

Spironolactone film-coated tablets may be prescribed by your doctor for the treatment of:
- accumulation of fluid in the tissues as a result of heart disorders;
- severe heart failure (NYHA III-IV)
- raised blood pressure as an adjunct to a salt-free diet and diuretics;
- certain kidney disorders;
- accumulation of fluid in the tissues in the abdominal cavity.

Spironolactone film-coated tablets may also be used:
during medical investigations (diagnostics) to confirm the presence of disorders in which too high a level of aldosterone is produced in the adrenal cortex (known as Conn's disease) and treatment.

Children should only be treated under guidance of a paediatric specialist.

2. What you need to know before you take Spironolactone film-coated tablets

Do not take Spironolactone film-coated tablets

- if you are allergic to spironolactone or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from severely impaired kidney function or from a sudden or rapidly deteriorating kidney disease, including cases in which no urine, or very little urine, is being produced.
- if you have low blood sodium levels (hyponatraemia)
- if you have hyperkalaemia (raised blood potassium levels) or any other conditions associated with hyperkalaemia
- if you are are taking potassium-sparing diuretics (including eplerenone) or potassium-supplements, or dual-RAAS blockade with the combination of an angiotensin converting enzyme (ACE) inhibitor and an angiotensin receptor blocker (ARB).

Children

Children with moderate to severe kidney disease must not take Spironolactone film-coated tablets.

Take special care with Spironolactone film-coated tablets

- if you suffer from kidney disease especially children with hypertension. Your doctor will routinely assess you.

Warnings and precautions

Talk to your doctor or pharmacist before taking Spironolactone film-coated tablets

- if you need to use Spironolactone film-coated tablets for a long time; your doctor should perform regular follow-up checks (for example on the levels of potassium and sodium in your blood), especially if you are elderly.
- if you have a liver disorder; your doctor should exercise caution when treating you;
- if you have a kidney disorder; your doctor should exercise caution when treating you;
- if you have a raised level of potassium in the blood or impaired kidney function; administration of Spironacton Accord is not advised (see also “Do not take Spironolactone film-coated tablets”);
- if you have severe renal dysfunction which is being simultaneously treated with potassium supplements, since sever hyperkalaemia can occur which can result in cardiac arrest (sometimes fatal).
- if you use certain diuretics, called potassium-sparing diuretics (such as amiloride and triamterene); concomitant use with Spironolactone film-coated tablet is contra-indicated, because the risk of excessively high levels of potassium in the blood (hyperkalaemia) is increased.
- in the case of long-term treatment of young patients with Spironolactone film-coated tablets, your doctor should weigh the advantages carefully against the long-term disadvantages.
- Concomitant administration of Spironolactone Accord 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.

Tell your doctor if one of the above warnings applies to you, or has done so in the past.

Other medicines and Spironolactone film-coated tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, your doctor may wish to alter your dose of Spironolactone film-coated tablets if you are taking any of the following.

- medicines for high blood pressure including ACE inhibitors, ganglion-blocking drugs
- other diuretics
- non-steroidal anti-inflammatory drug (NSAID) such as aspirin or ibuprofen
- potassium supplements
- heparin or low molecular weight heparin (medicines used to prevent blood clots)
- drugs that inhibit blood coagulation (anticoagulants, 'blood thinners')noradrenaline (an agent with a stimulant effect on a particular part of the nervous system (sympathomimetic))
- lithium (used to treat depression)
- digoxin (used in the treatment of various heart conditions)
- alcohol, barbiturates or narcotics
- medicines known to cause hyperkalaemia (raised blood potassium levels)
- Cholestyramine (used for reducing cholesterol levels in the blood)
- Corticosteroids, ACTH (prescribed for different epileptic conditions)
- ammonium chloride (e.g. in liquorice)
- Ciclosporin
- trimethoprim and trimethoprim-sulfamethoxazole

Spironolactone film-coated tablets with food
The action of Spironolactone is not affected by food.

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.
Sprinonolactone should not be used during pregnancy.
Sprinonolactone should only be used during breast-feeding if clearly needed.
You should discuss the use of Sprinonolactone with your doctor, who will advise you to consider an alternative method of feeding your baby while you are taking this medicine.
Spironolactone may induce impotence and menstrual irregularities.

Driving and using machines
Side effects such as dizziness, headache and confusion can sometimes occur while you are using Spironolactone film-coated tablets. In this case, do not drive a vehicle or use machines.

Spironolactone film-coated tablets contains lactose
This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Spironolactone film-coated tablets

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 recommended dose is:

<u>Adults</u>

The recommended dosage is 100 mg daily, administered as one or several doses. The adult dose varies from 25mg to 400mg spironolactone a day. If you are not sure how much to take, ask your doctor or pharmacist.

You should take the tablets with meals. If the total dose is more than 100 mg per day, the dose must be administered in divided doses spread throughout the day.

Use in children
The recommended dose is 3 mg per kg body weight daily, in several divided doses. In order to make it easier for children to take, the tablets may first be ground or crushed and then suspended in a glass of water by stirring.

The elderly
It is recommended that elderly patients should be started on the lowest possible dose, increasing this gradually until the desired effect is achieved. Caution and regular medical checks are advised, especially in the event of renal impairment.

Remember to take your medicine. Taking your tablets at the same time each day gives the best effect. It also helps you remember when you should take the tablets.

If you take more Spironolactone film-coated tablets than you should
If you have taken too much Spironolactone film-coated tablets, contact your doctor or pharmacist immediately. Keep the pack so that the doctor can see what medicine you have taken.
Symptoms of overdose can include nause and vomiting, and (more rarely) drowsiness, confusion, skin rash or diarrhoea. Disturbance of the fluid and salt balance and dehydration may occur.

If you forget to take Spironolactone film-coated tablets
If you have forgotten to take a dose, take it as soon as possible unless it is almost time to take the next dose, in which case you should not take the forgotten dose, but continue according to the schedule prescribed. Do not take a double dose to make up for a forgotten dose. Ask your doctor or pharmacist if you are not sure.

If you stop taking Spironolactone film-coated tablets
If you stop using Spironolactone film-coated tablets, the original symptoms may return. Always contact your doctor if you want to stop using the medicine.

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.

The side effects depend on the dose and the duration of treatment.
The most common side effects are hyperkalaemia, reproductive system and breast disorders, including gynaecomastia. Gynaecomastia appears to be related to both dosage level and duration of therapy and is usually reversible as soon as the treatment is discontinued. Other very common undesirable side effects are headache, digestive disturbances, diarrhoea, fatigue and drowsiness.

Very common: may affect more than 1 in 10 people

- Hyperkalaemia in patients with severe renal dysfunction who are receiving concomitant treatment with potassium supplements
- Headache
- Indigestion, diarrhoea
- Men: reduced libido, erectile dysfunction, impotence, enlargement of the mammary glands (gynaecomastia);
- Women: breast disorders, tenderness of the breasts, menstrual disorders, deepening of the voice (in many cases irreversible)
- Fatigue, drowsiness

Common: may affect up to 1 in 10 people
- Hyponatraemia (in particular during combined intensive therapy with thiazide diuretics), hyperkalaemia in (1) patients with severe renal dysfunction, (2) patients receiving treatment with ACE inhibitors or potassium chloride, (3) the elderly, and (4) diabetic patients
- Nausea and vomiting
- Women: changes in vaginal secretions, reduced libido, absence of periods (amenorrhoea), post-menopausal bleeding
- Weakness, somnolence (lethargy) in patients with cirrhosis, sensations of tickling, itching or tingling for which there is no cause (paraesthesia)
- General weakness

Uncommon: may affect up to 1 in 100 people
- Acidity of the blood (acidosis) in patients with liver problems
- Confusion
- Skin rash, urticaria, erythema, chloasma, generalised itchiness
- Muscle spasms
- Leg cramps
- Elevated serum creatinine levels

Rare: may affect up to 1 in 1,000 people
- Very severe blood abnormalities (deficiency of white blood cells) accompanied by sudden high fever, severe throat pain and mouth ulcers (agranulocytosis), blood abnormality (platelet deficiency) accompanied by bruises and tendency to bleed (thrombocytopenia),
- Allergic reactions
- Insufficient fluid in the tissues (dehydration), porphyria, temporary increase in nitrogen levels in the blood and urine, elevated uric acid levels in the blood (hyperuricemia), This can in susceptible patients lead to gout attacks.
- Paralysis, paraplegia of the limbs due to hyperkalaemia

Very rare: may affect up to 1 in 10,000 people
- Breast cancer
- Inflammation of the vessel walls (vasculitis)
- Gastric inflammation, gastric ulcers, gastrointestinal haemorrhage, cramps
- Hepatitis
- Alopecia, eczema, erythema annulare centrifugum (EAC)
- Systemic lupus erythematosus (SLE)
- Acute renal failure
- Excessive hair growth (hypertrichosis)
- Bone softening (osteomalacia)

Not known: frequency cannot be estimated from the available data

- Slight androgenic effects, including hirsutism.
- Reversible hyperchloraemic metabolic acidosis – usually accompanied by hyperkalaemia – has been reported in some patients with decompensated hepatic cirrhosis, even where renal function was normal.
- Dizziness, ataxia
- Mild hypotension
- Itchiness and blistering of the skin around the lips and the rest of the body (Stevens-Johnson syndrome)
- Detachment of the top layer of skin from the lower layers of skin, all over the body (toxic epidermal necrolysis)
- Skin rash, fever and swelling (which could be symptoms of something more serious, drug rash and eosinophilia and systemic symptoms)
- Pemphigoid (condition presenting with fluid-filled blisters on the skin)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Spironolactone film-coated tablets

- Keep this medicine out of the sight and reach of children.
- This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light.
- Do not use this medicine after the expiry date which is stated on the carton and blister 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 protect the environment.

6. Contents of the pack and other information

What Spironolactone film-coated tablets contains

The active substance is spironolactone. Spironolactone film-coated tablets contains 25 mg, 50 mg or 100 mg spironolactone.

The other ingredients are:
Core of the tablet

Lactose monohydrate, pregelatinised corn starch , calcium hydrogen phosphate, anhydrous, povidone K25, peppermint oil, purified talc, silica, colloidal anhydrous, magnesium stearate (E470b).

Film coating
Hypromellose, macrogol, titanium dioxide (E171).

What Spironolactone film-coated tablets looks like and contents of the pack
Spironolactone 25 mg, film-coated tablets are white to pale white, round, biconvex tablets printed with 'AD' on one side and no imprint on the other side. 25mg tablet diameter is approximately 8.1 mm.

Spironolactone 50 mg, film-coated tablets are white to pale white, round, biconvex tablets printed with 'AE' on one side and no imprint on the other side. 50mg tablet diameter is approximately 10.1 mm.

Spironolactone 100 mg, film-coated tablets are white to pale white, round, biconvex tablets printed with 'AF' on one side and no imprint on the other side. 100mg tablet diameter is approximately 11.2 mm.

Tablets are packed in PVC-Aluminium blister pack & HDPE bottle pack

Pack sizes:
Blister pack: 20, 28, 30, 50, 60, 90 and 100 tablets in blister.
HDPE bottle: 250, 500 and 1000 tablets (for hospital or dose dispensing use only)

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Accord Healthcare Ireland Limited
Euro House
Euro Business Park
Little Island
Cork T45 K857
Ireland

Manufacturer
Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

Accord Healthcare B.V.,
Winthontlaan 200,
3526 KV Utrecht,
The Netherlands

This medicinal product is authorised in the member states of the EEA under the following names:

Country	**Invented Name**
The Natherland	Spironolacton Accord 25mg/50 mg/100 mg filmomhulde tabletten
Bulgaria	Spironolactone Accord 25 mg/50 mg/100 mg филмирани таблетки
Cyprus	Spironolactone Accord 25 mg/100 mg Επικαλυμμένα με λεπτό υμένιο δισκία
Germany	Spironolacton Accord 25 mg/50 mg/100 mg Filmtabletten
Denmark	Spironolactone Accord 25 mg/50 mg/100 mg filmovertrukne tabletter

Estonia	Spironolactone Accord
Spain	Spironolactone Accord 25 mg/100 mg comprimidos recubiertos con película
Ireland	Spironolactone 25 mg/50 mg/100 mg film-coated tablets
Lithuania	Spironolactone Accord 25 mg/50 mg/100 mg plėvele dengtos tabletės
Latvia	Spironolactone Accord 25 mg/50 mg/100 mg apvalkotās tabletes
Malta	Spironolactone 25 mg/100 mg film-coated tablets
Poland	Ismian
Sweden	Spironolactone Accord 25 mg/50 mg/100 mg filmdragerad tablet
Slovakia	Spironolactone Accord 25 mg/50 mg/100 mg filmom obalené tablety
United Kingdom	Spironolactone 25 mg/50 mg/100 mg film-coated tablets

This leaflet was last revised in 11/2021.