

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 if their 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
2. What you need to know before you take Spironolactone film-coated tablets
3. How to take Spironolactone film-coated tablets
4. Possible side effects
5. How to store Spironolactone film-coated tablets
6. Contents of the pack and other information

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 Addison's disease (a hormone deficiency characterised by extreme weakness, loss of weight and low blood pressure)
- if you have hyperkalaemia (raised blood potassium levels) or any other conditions associated with hyperkalaemia
- if you 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 with moderate to severe kidney disease must not take Spironolactone film-coated tablets.

Warnings and precautions

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

- Patients who are being treated with spironolactone require regular supervision with monitoring of fluid and electrolyte state, especially in the elderly and/or in patients with pre-existing impaired renal or hepatic function
- if you have difficulty passing urine,
- 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 severe hyperkalaemia can occur which can result in cardiac arrest (sometimes fatal).
- 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.
- if you have a disease that can result in a disturbance to the electrolyte (minerals in your blood such as potassium and sodium) balance in your blood
- if you suffer from any increase or decrease of electrolytes in your blood such as potassium or sodium
- if you have severe heart failure
- if you are taking any other water tablets (diuretics) in combination with Spironolactone film-coated tablets which may cause low sodium levels (hyponatraemia) in the blood
- Concomitant administration of Spironolactone film-coated tablets 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.

Children

Spironolactone should be used with caution in children with high blood pressure and mild kidney disease. Your doctor will routinely assess you. (Children with moderate to severe kidney disease must not take spironolactone).

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, ibuprofen or mefenamic acid
- potassium supplements
- heparin or low molecular weight heparin (medicines used to prevent blood clots)
- drugs that inhibit blood coagulation (anticoagulants, ‘blood thinners’),
- 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
- carbenoxolone, used for the treatment of gastro-esophageal reflux disease
- noradrenaline, used for the treatment of acute low blood pressure
- cardiac glycosides, used in the treatment of heart failure
- medicine for regional or general anaesthesia
- trimethoprim and trimethoprim-sulfamethoxazole
- if you are using abiraterone for treatment of prostate cancer.

Tell your doctor, if you are using mitotane for treatment of malignant tumours of the adrenal glands. This medicine should not be used together with mitotane.

If you are going to have an operation where you will be given an anaesthetic, tell the doctor in charge that you are taking Spironolactone film-coated tablets.

Spironolactone film-coated tablets with food

This medicine should be taken with 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.

Spironolactone should not be used during pregnancy unless your doctor considers this required.
Spironolactone should not be used if you are breast-feeding.

You should discuss the use of Spironolactone with your doctor, who will advise you to consider an alternative method of feeding your baby while you are taking this medicine.

Spironolactone may impair fertility and 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:

Adults

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.

The symptoms of an overdose can include nausea and vomiting, and (more rarely) drowsiness, confusion, diarrhoea or skin rashes that will appear as flat red areas of skin with overlapping small raised bumps. . Disturbance of the fluid and salt balance and dehydration may occur. Changes in your blood sodium and potassium levels may leave you feeling weak and suffering from tingling, prickling or numbness of the skin and/or muscle spasms but these symptoms are unlikely to be associated with severe over dosage.

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.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, the symptoms can be severe.

- itchininess 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 skin, all over the body (toxic epidermal necrolysis - TEN)
- skin rash, fever and swelling (which could be symptoms of something more serious, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- yellow skin and eyes (jaundice; spironolactone can cause impairment of liver function)
- irregular heartbeat that can be fatal, tingling sensation, paralysis (loss of muscle function) or difficulty in breathing; which may be symptoms of raised potassium levels in your blood. Your doctor will conduct regular blood tests to monitor potassium and other electrolyte levels. Your doctor may stop your treatment if necessary.

Other side effects

Very common: may affect more than 1 in 10 people

- Raised potassium in the blood

Common: may affect up to 1 in 10 people

- confusion
- dizziness
- feeling sick
- itching of the skin
- rash

- muscle or leg cramps
- kidney failure or abnormal function
- breast enlargement in men
- breast pain (in men)
- feeling generally unwell

Uncommon: may affect up to 1 in 100 people

- changes in the breast such as breast lumps
- disturbances in body electrolytes such as high blood calcium
- abnormal functioning of the liver
- skin allergy with development of itchiness and hives, nettle like rash
- menstrual problems in women
- breast pain (in women)

Not known: frequency cannot be estimated from the available data

- lowered white blood cell count in blood
- reduced number of cells that fight infection –white blood cells which make infections more likely
- reduced number of cells carrying oxygen (anaemia)
- reduced number of cells that help with blood clotting or increased eosinophil count in the blood (eosinophilia) which increases risk of bleeding or bruising or causes purple spots on the skin (purpura)
- change in sex drive for both men and women
- temporary impotence in men
- digestion problems, stomach upset
- skin condition presenting with fluid-filled blisters (pemphigoid)
- hair loss
- excessive hair growth
- headache
- drowsiness
- general weakness or lethargy and problems coordinating muscle movements (ataxia)
- fever

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

Website: www.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

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This medicinal product is authorised in the Member States of the Economic European Area and in the United Kingdom (Northern Ireland) under the following names:

Name of the member state	Name of the medicine
The Netherlands	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 April 2025.