

Spiro 25mg Tablet®

Spironolactone 25mg

Consumer Medication Information Leaflet (RiMUP)

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What Spiro is used for

Spiro is used:

- To treat essential hypertension (high blood pressure with an unknown cause)
- To treat oedematous disorders (swelling with fluid), including congestive cardiac failure
- For the diagnosis and treatment of primary aldosteronism (a hormone disorder causing fluid retention)
- As add-on therapy in malignant hypertension (a very serious form of high blood pressure)
- Where there is a low amount of potassium (a mineral) in the blood caused by another diuretic (fluid-removing medicine)

Spironolactone improves the blood pressure lowering action of thiazide diuretics while at the same time reducing or preventing potassium loss due to these medicines.

- For the prevention of low amounts of potassium in the blood in patients taking digitalis (a type of heart drug)
- For the treatment of hirsutism (excess body hair in women)

Spiro has a moderate ability to act against male sex hormones (anti-androgenic effect). Because of this, Spiro is effective in the treatment of female hirsutism (excess body hair). It reduces hair growth, thickness and hair colour. Increased urine flow is unlikely to be a problem when Spiro is used to treat hirsutism. This is because Spiro levels are not normally high in patients with hirsutism

How Spiro works

Spiro works by working against a hormone called aldosterone. Too much aldosterone causes increased amounts of sodium (a mineral) and water to be retained by the kidneys, while too much potassium is removed from the body.

Spironolactone works against the effects of aldosterone. Spironolactone acts by removing excess fluid and by lowering blood pressure. It may be given alone or with other diuretics (fluid-removing medicines). It improves the effectiveness of other medicines used to lower blood pressure

Spironolactone also has a moderate ability to act against male sex hormones (anti-androgenic effect)

Before you use Spiro

- When you must not take it

Do not use Spiro if:

- you are pregnant or think you might be pregnant. Spiro should not be used during pregnancy due to possible effects on the developing baby (fetus).
- you are breast feeding the drug may appear in the breast milk and be passed to the infant.
- you are allergic to Spironolactone or to any of the tablet ingredients listed at the end of this leaflet

If you have an allergic reaction you may get a skin rash, have difficulty in breathing, or become faint.

- you have severe kidney disease or are not passing urine
- you have hyperkalaemia (high levels of potassium in the blood). Hyperkalaemia is very serious if you also suffer from severe heart failure. Symptoms of severe heart failure are shortness of breath and swelling of the legs from fluid build.
- you have Addison's disease (a condition where the adrenal glands do not work properly)

Do not take Spiro with potassium supplements or potassium

containing salt substitutes or with potassium sparing diuretics

- Before you start to use it

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition, including:
 - o potassium supplements
 - o potassium containing salt substitutes
 - o potassium sparing diuretics
 - o other medicines for high blood pressure.
- are allergic to any other medicines, foods, preservatives or dyes.

Taking other medicines

Some of the medicines that may affect Spiro or be affected by Spiro include:

- other medicines used to treat high blood pressure
- diuretics, which are fluid removing medicines, also known as, water tablets
- digoxin, a medicine used to treat heart conditions
- medicines to prevent blood clots.
- potassium supplements or potassium containing salt substitutes or potassium sparing diuretics.
- dietary salt substitutes as many of these contain potassium
- cholestyramine, a medicine used to lower cholesterol levels in the blood
- ammonium chloride, which is contained in some cough and cold medicines
- Aspirin
- non-steroidal anti-inflammatory (NSAIDS) medicines or other medicines which are used to relieve pain, swelling and other symptoms of inflammation, including arthritis.
- regional or general anaesthetics.
- abiraterone treatment in prostate cancer patients.

These medicines may be affected by Spironolactone or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different

medicines. Your doctor or pharmacist has a more complete list of medicines to avoid while taking Spiro.

How to use Spiro

- How much to use

Daily doses of Spiro in adults can range from 25mg to 40mg. Depending on the dose and your condition, Spiro may be taken once a day or divided into separate doses

In the treatment of hirsutism (excess body hair) in females, your doctor may tell you to take Spiro every day or in repeating cycles with a break in between

Follow your doctor's instructions exactly regarding the dose you should take and how often you should take it

Doses of Spiro in children are measured accordingly to body weight and will be calculated by your doctor

- When to use it

Take Spiro Tablet as your doctor has prescribed.

How long to use it

Continue taking your medicine for as long as you doctor tells you

- If you forget to use it

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints

- If you use too much (overdose)

Immediately telephone your doctor or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Spironolactone.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers for these places handy.

Overdose may cause nausea and vomiting. Sometimes, drowsiness,

mental confusion, rash, diarrhoea or dehydration may occur.

While you are using it

- Things you must do

Take Spiro exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Spiro.

This is especially important if you are going to receive an anaesthetic agent while being treated with Spiro.

If you are about to have any blood tests tell your doctor that you are taking Spiro.

Spiro may interfere with the results of some tests.

Tell your doctor if you're taking other types of medicines to treat high blood pressure.

Tell your doctor if you're taking medicines to prevent blood clots.

Tell your doctor if you become pregnant while you are taking Spiro.

If it is possible for you to become pregnant, you should use adequate contraception while you are taking Spironolactone.

Examples of adequate contraception are oral contraceptives ("the Pill") or intrauterine devices (IUDs)

Stop taking Spiro if you become pregnant or you think you may be pregnant.

Go to your doctor regularly for check-up.

Your doctor may do blood tests to check your sodium and potassium levels and see how your kidneys are working. Your doctor may do the blood test weekly at the start of your treatment, monthly for the first 3 months of treatment then quarterly for a year, and then every 6 months when increasing your dose.

You may need to stop taking Spironolactone if your blood is high in potassium or if your kidneys are not working properly.

- Things you must not do

Do not stop using this medicine suddenly.

Do not take potassium supplements or use substitutes potassium. that contain

Do not consume a diet rich in potassium. Dried fruit, bananas and oranges are some foods that contain high amounts of potassium. Consuming some of these foods is usually safe but do not consume excessive amounts.

If you are taking Spiro, too much potassium can cause serious problems, such as disturbances to the heart rhythm.

- Things to be careful of

Do not drive or operate machinery until you know how Spiro affects you.

Spiro may cause drowsiness or dizziness in some people and may affect alertness.

Do not give this medicine to anyone else even if their symptoms seem similar to yours.

Driving or using machines

This medicine may affect your ability to drive or use machines. If you feel dizzy, drowsy or have blurry vision, do not drive or use machines until these symptoms have worn off.

Side effects

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

- Cramping or diarrhoea
- nausea or vomiting
- drowsiness, lethargy or generally feeling unwell
- skin rash or itchiness
- peeling skin or skin redness
- fever or sore throat
- unusual hair loss or thinning
- excessive hair growth

Speak to your doctor if you have any of these common side effects and they worry you.

Serious side effects

- frequent infection such as fever, severe chills, sore throat or mouth ulcers

A few cases of agranulocytosis (lack of white blood cells) have been reported in patients taking Spiro.

- breast enlargement
Breast enlargement may occur in men taking Spiro. This normally goes away when Spiro is stopped. In rare instances some breast enlargement may persist.

- breast lumps

Breast lumps and breast cancer have been reported in patients taking Spiro although. Spiro has not been shown to cause breast cancer.

- breast pain
- irregular periods or no periods
- post-menopausal bleeding
- change in sex drive
- impotence (inability to achieve or maintain an erection)
- stomach bleeding, ulcers or gastritis (inflammation of the stomach)
- unsteadiness when walking
- leg cramps
- headache
- mental confusion or dizziness
- shortness of breath and swelling of the legs from fluid build

May be due to hyperkalaemia (high levels of potassium in the blood) that is very serious.

Tell your doctor or pharmacist if you anything else that is making you feel unwell. Other side effects not listed above may also occur in some people

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.moh.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI).

Storage and Disposal of Spiro**- Storage**

Keep your medicine in its original packaging until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Keep your medicine in a dry place where the temperature will stay below 30°C.

Keep Spiro 25mg Tablet where children cannot reach it.

- Disposal

If your doctor tells you to stop taking Spiro Tablet or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over

Product Description**- What it looks like**

Spirolactone 25mg tablet is 8mm in diameter, round, convex, marked with 'SPIRO' and scored at one side, plain on the other side, orange tablet.

- Ingredients

Active ingredient:

- Spironolactone

Inactive ingredients:

- Corn starch
- Yellow colouring
- Lactose monohydrate

- Magnesium stearate

- MAL number

MAL19870234AZ

Manufacturer

Duopharma Manufacturing (Bangi) Sdn. Bhd

Lot No. 2&4, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bangi Industrial Estate, Selangor, Malaysia

Product Registration Holder

Duopharma Manufacturing (Bnagi) Sdn. Bhd

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Date of Revision

28/05/2024

Serial Number

NPRA (R2/1)200615/458