

SPIRONOLACTONE TABLET®

Spirolactone 25mg

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What Spirolactone is used for

Spirolactone 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)

Spirolactone 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 treatment of hirsutism (excess body hair in women)

Spirolactone 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 Spirolactone is used to treat hirsutism. This is because aldosterone levels are not normally high in patients with hirsutism.

How Spirolactone works

Spirolactone acts 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.

Spirolactone works against the effects of aldosterone. Spirolactone 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.

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

Before you use Spirolactone

When you must not take it

Do not use Spirolactone if:

- you are pregnant or think you might be pregnant Spirolactone 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 Spirolactone 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 Spirolactone with potassium supplements or potassium

containing salt substitutes or with potassium sparing diuretics.

Before you start to use it

You must tell your doctor if:

- you are already taking medicines for high blood pressure
- you are allergic to any other medicines, or any foods, dyes or preservatives
- you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Taking other medicines

Some of the medicines that may affect Spirolactone or be affected by Spirolactone 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.
- 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.

These medicines may be affected by Spirolactone 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 Spirolactone.

How to use Spironolactone

How much to use

Daily doses of Spironolactone in adults can range from 25 mg to 400mg. Depending on the dose and your condition, Spironolactone 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 Spironolactone 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 Spironolactone in children are measured according to body weight and will be calculated by your doctor.

When to use it

Take Spironolactone Tablet as your doctor has prescribed.

How long to use it

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

If you forget to use it

If you forget to take Spironolactone, do not try to make up for missed doses by taking more than one dose at a time.

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 Spironolactone exactly as your doctor has prescribed.

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

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

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

Spironolactone 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 Spironolactone.

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 intra-uterine devices (IUDs).

Stop taking Spironolactone 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 take potassium supplements or use salt substitutes that contain potassium.

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 spironolactone, 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 Spironolactone affects you.

Spironolactone 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.

Side effects

Like all medicines, Spironolactone tablet can cause side effects, although not everyone gets them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- cramping or diarrhoea
- nausea or vomiting
- drowsiness, lethargy or generally feeling unwell
- skin rash or itchiness
- fever
- unusual hair loss or thinning
- excessive hair growth

Tell your doctor or pharmacist if you notice 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 calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Spironolactone

Storage

Keep your medicine in the bottle or pack until it is time to take them.

If you take the medicine out of the bottle or pack they will not keep well.

Keep the medicine in a cool dry place where the temperature stays below 30 degrees C.

Keep Spironolactone Tablet where children cannot reach it.

Disposal

If your doctor tells you to stop taking Spironolactone 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

Spironolactone 25mg tablet is 8mm in diameter, round, convex, scored, marked 'UPHA SPN' orange tablet.

Ingredients

Active ingredient:

- Spironolactone

Inactive ingredients:

- Corn starch
- Yellow colouring
- Lactose monohydrate
- Magnesium stearate

MAL number

MAL19870234A

Manufacturer

UPHA PHARMACEUTICAL MFG (M)
SDN BHD (53667-M)
Lot 2&4, Jalan P/7, Section 13,
Bangi Industrial Estate,
43650 Selangor Darul Ehsan

Product Registration Holder

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SDN BHD (53667-M)
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Date of Revision

21/1/2014