

SPIRACTIN

Spironolactone 25mg and 100mg Tablets



What is in this leaflet

Please read this leaflet carefully before you start taking SPIRACTIN.

This leaflet answers some common questions about SPIRACTIN.

It does not contain all the information available on this medicine. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SPIRACTIN against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What SPIRACTIN is used for and how it works

SPIRACTIN tablets contain the active ingredient spironolactone. It belongs to a group of medicines known as diuretics.

SPIRACTIN is used to lower high blood pressure, also called hypertension. It treats fluid build-up in the body which can occur in some heart, liver or kidney conditions. It helps bring potassium levels in the blood back to normal when the levels become too low. It also treats a condition called hyperaldosteronism and excess facial or body hair in women.

Your doctor may, however, prescribe SPIRACTIN for another reason.

There is no evidence that SPIRACTIN is addictive.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

SPIRACTIN is available on prescription from your doctor.

Before you take SPIRACTIN

When you must not take it

Do not take SPIRACTIN if:

- You are allergic to spironolactone or any other ingredients listed at the end of this leaflet
- You have kidney problems
- You have high potassium levels in your blood
- You are not producing or passing urine
- Addison's disease (a condition in which the adrenal glands don't produce enough hormones)

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

The active ingredient in SPIRACTIN passes into breast

milk and there is a possibility that your baby may be affected.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- Kidney or liver problems
- Take medication that may increase potassium levels in the blood.

If you have not told your doctor about any of the above, tell them before you start taking SPIRACTIN.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop,

You should also tell any health professional who is prescribing a new medication for you that you are taking SPIRACTIN.

Some medicines that may interfere with SPIRACTIN include:

- Medicines used to treat high blood pressure and some other heart conditions
- Diuretics, which are fluid removing medicines also known as water tablets
- Digoxin, a medicine used to treat heart failure
- Tablets, preparations or supplements which contain potassium
- Salt substitutes which contain potassium
- Aspirin
- Non-steroidal anti-inflammatory drugs (NSAIDs), or other medicines used to relieve pain, swelling or other symptoms of inflammation, including arthritis
- Carbenoxolone, a medicine used to treat mouth ulcers
- Regional or general anaesthetics
- Cholestyramine, a medicine used to lower cholesterol levels in the blood
- Ammonium chloride, which is contained in some cough and cold medicines
- Heparin, a medicine used to thin the blood

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

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking SPIRACTIN.

How to take SPIRACTIN

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much SPIRACTIN you need to take. It is important that you take

SPIRACTIN as directed by your doctor. Do not take more than the recommended dose.

The usual dose for adults with high blood pressure is 50mg to 100mg per day which may be gradually increased at two weekly intervals up to 200mg per day. The daily dose may be given either in divided doses or as a single daily dose. Treatment should be continued for at least two weeks since an adequate response may not occur before this time.

For other conditions, your doctor will tell you how many tablets you need to take each day and when to take them. This depends on your condition and whether or not you are taking other medicines.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking SPIRACTIN for as long as your doctor tells you to.

If you forget to take it

If you forget to take SPIRACTIN, do not try to make up for missed doses by taking more than one dose at a time. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

While you are taking SPIRACTIN

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking SPIRACTIN.

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

Tell your doctor if you develop a skin rash or hives, or you become pregnant while taking SPIRACTIN.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking SPIRACTIN. It may affect other medicines used during surgery.

If you are going to have any blood tests, tell your doctor that you are taking SPIRACTIN. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take SPIRACTIN to treat any other complaints unless your doctor tells you to.

Do not stop taking SPIRACTIN or lower the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours or the same condition as you.

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 SPIRACTIN, too much potassium can cause serious problems, such as disturbances to the heart rhythm.

Things to be careful of

Be careful driving or operating machinery until you know how SPIRACTIN affects you.

SPIRACTIN may cause dizziness, drowsiness or confusion in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Children should be careful when riding bicycles or climbing trees.

In case of overdose

If you take too much (overdose)

You should only take the number of tablets that you have been told.

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any SPIRACTIN by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Take the container of SPIRACTIN with you if you can.

Keep telephone numbers for these places handy.

Symptoms of an overdose may include:

- Nausea and vomiting,
- Dizziness
- Drowsiness
- Mental confusion
- Skin rash
- Diarrhoea
- Pins-and-needles
- Weakness
- Paralysis
- Involuntary contraction of muscles.

Side effects

Tell your pharmacist or doctor as soon as possible if you do

not feel well while you are taking SPIRACTIN. This medicine helps most people, but it may have unwanted side effects in a few people.

All medicines can have some unwanted effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

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

- Feeling sick, vomiting
- Stomach cramps or pain, diarrhoea
- Headache
- Drowsiness, lack of energy
- Unusual hair loss or thinning
- Excessive hair growth

Tell your doctor as soon as possible if you notice any of the following:

- Lumps in the breasts
- Breast enlargement in men
- Breast pain
- Confusion or dizziness
- Leg cramps
- Unsteadiness when walking
- Signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- Change in sex drive
- Impotence (inability to achieve or maintain an erection)
- Menstrual period changes in women
- Post-menopausal bleeding

The above list includes serious side effects that may require medical attention.

Tell your doctor immediately if you experience any of the following:

- Vomiting blood or material that looks like coffee grounds
- Bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea

- Shortness of breath and swelling of the legs from fluid build-up (may be due to hyperkalaemia, which is very serious)
- Blistering, rash, hives, peeling or painful red areas of skin. This may be accompanied by fever, chills, aching muscles and generally feeling unwell.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Some of these side effects such as high potassium levels, changes in liver function can be found when your doctor does tests from time to time to check your progress.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking SPIRACTIN

Keep your tablets in the bottle until it is time to take them.

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

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store SPIRACTIN or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking SPIRACTIN or if the tablets have passed the expiry date, ask your pharmacist what to do with any medicine that is left over.

Product description

What SPIRACTIN tablets look like

SPIRACTIN 25mg tablets are pale orange round tablets, marked with α on one side and SP on the other.

1

SPIRACTIN 100mg tablets are pale orange round tablets, marked with α on one side and SP on the other.

2

Ingredients

Active ingredient:

Each SPIRACTIN tablet contains 25 mg or 100 mg of spironolactone as the active ingredient.

Inactive ingredients:

SPIRACTIN also contains:

- Quinoline yellow
- Sunset yellow
- Erythrosine
- Polysorbate
- Peppermint oil
- Povidone
- Microcrystalline cellulose
- Starch
- Sodium starch glycollate
- Talc
- Magnesium stearate
- Lactose

Sulphites may be present in this product in trace amounts.

This medicine does not contain gluten.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: 0800 579 811

Date of information

21 October 2020
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