

SPIRACTIN

contains the active ingredient spironolactone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SPIRACTIN.

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

All medicines have benefits and risks. 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 taking this medicine, talk to your doctor or pharmacist.

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

What SPIRACTIN is used for

SPIRACTIN is used:

- to treat essential hypertension (high blood pressure with an unknown cause)
- to treat oedematous disorders (swelling with fluid), including congestive cardiac failure
- to help bring potassium levels in the blood back to normal when the levels become too low
- to treat hyperaldosteronism (a hormone disorder causing fluid retention)
- as add on therapy in malignant hypertension (a very serious form of high blood pressure)
- treat excess facial or body hair in women.

Ask your doctor if you have any questions about why this

medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

There is no evidence that SPIRACTIN is addictive.

How SPIRACTIN works

In fluid build-up and high blood pressure

SPIRACTIN is a fluid tablet or diuretic. It helps reduce the amount of excess fluid in the body by increasing the amount of urine produced. This also helps to lower blood pressure.

In hyperaldosteronism and low potassium levels in the blood

In hyperaldosteronism, the adrenal glands produce too much of a hormone called aldosterone. SPIRACTIN works by stopping the effects of aldosterone.

By stopping the effects of aldosterone, SPIRACTIN also helps to maintain normal levels of potassium in the blood by retaining potassium in the body.

In women with excess hair

All women produce small amounts of the male sex hormone, testosterone. Women with excess facial or body hair tend to be especially sensitive to the action of testosterone on hair growth. SPIRACTIN reduces the growth of hair by stopping the effects of testosterone. Increased urine flow is unlikely to be a problem when SPIRACTIN is used to treat hirsutism. This is because aldosterone levels are not normally high in patients with hirsutism.

Before you take SPIRACTIN

When you must not take it

Do not take SPIRACTIN if you are allergic to any medicine containing spironolactone or any of the ingredients listed at the end of this leaflet.

Some of the 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 SPIRACTIN if you have any of the following medical conditions:

- high potassium levels in your blood (hyperkalaemia)
- severe kidney disease or not passing urine.
- Addison's disease, a condition where the adrenal glands do not work properly.

The safety of SPIRACTIN for the treatment of hirsutism in women of child-bearing age has not been established by specific studies.

Your doctor may recommend combined use with oral contraceptives to provide both regular menstrual cycles and adequate contraception.

Do not take this medicine if you are pregnant or think you might be pregnant.

SPIRACTIN can affect your developing baby if you take it during pregnancy.

Do not take this medicine if you are breastfeeding.

SPIRACTIN passes into breast milk and may affect your baby.

Do not take this medicine after the expiry date printed on the pack or if 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 start to take it

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

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

- liver problems
- kidney problems
- severe heart failure.

Tell your doctor if you plan to become pregnant or breastfeed.

Tell your doctor if you plan to have surgery.

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

Taking other medicines

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

Some medicines and SPIRACTIN may interfere with each other. These include:

- other medicines used to treat high blood pressure, including ACE inhibitors
- diuretics, which are fluid removing medicines also known as water tablets
- digoxin, a medicine used to treat heart conditions

- potassium supplements or potassium-containing salt substitutes
- colestyramine, a medicine used to lower cholesterol levels in the blood
- ammonium chloride, which is contained in some cough and cold medicines
- medicines to prevent blood clots, including aspirin
- non-steroidal anti-inflammatory drugs (NSAIDs), or other medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis (e.g. aspirin, indometacin or mefenamic acid)
- carbenoxolone, a medicine used to treat mouth ulcers
- regional or general anaesthetics.

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

Your doctor and pharmacist have 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 and 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 many tablets you need to take each day.

Daily doses of SPIRACTIN in adults can range from 25mg to 400mg. This depends on your

condition and whether or not you are taking other medicines.

Doses of SPIRACTIN in children are measured according to body weight and will be calculated by your doctor.

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

How to take it

Swallow the tablets with a glass of water.

When to take it

Depending on the dose and your condition, SPIRACTIN may be taken once a day or divided into separate doses.

Take SPIRACTIN with or immediately after food.

How long to take it for

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

The length of treatment will depend on your condition. SPIRACTIN is usually taken long term.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia telephone 13 11 26; New Zealand telephone 0800 POISON or 0800 764 766) for advice, or go to

Accident and Emergency at the nearest hospital if you think you or anyone else may have taken too much SPIRACTIN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much SPIRACTIN, you may feel drowsy, weak, confused or sick, vomit, have diarrhoea or pins and needles of the hands or feet.

While you are taking SPIRACTIN

Things you must do

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

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

This is especially important if you are going to receive an anaesthetic agent while being treated with SPIRACTIN. If you become pregnant while taking this medicine, tell your doctor immediately.

If it is possible for you to become pregnant, you should use adequate contraception while you are taking SPIRACTIN. Examples of adequate contraception are oral contraceptives ("the Pill") or intra-uterine devices (IUDs). Stop taking SPIRACTIN if you become pregnant or you think you may be pregnant.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

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

Your doctor may ask you to have blood tests to check your sodium and potassium levels and see how your kidneys are working.

Things you must not do

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

Do not give your medicine to anyone else, even if they have the same condition as you.

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

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.

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

Lifestyle measures that help reduce heart disease risk

By following these simple measures, you can further reduce the risk from heart disease.

- Quit smoking and avoid second-hand smoke.
- Limit alcohol intake.
- Enjoy healthy eating by:
 - eating plenty of vegetables and fruit;
 - reducing your saturated fat intake (eat less fatty meats, full fat dairy products, butter, coconut and palm oils, most

take-away foods, commercially-baked products).

- Be active. Progress, over time, to at least 30 minutes of moderate-intensity physical activity on 5 or more days each week. Can be accumulated in shorter bouts of 10 minutes duration. If you have been prescribed anti-angina medicine, carry it with you when being physically active.
- Maintain a healthy weight.
- Discuss your lifestyle and lifestyle plans with your doctor.
- For more information and tools to improve your heart health, call Heartline, the Heart Foundation's national telephone information service, on 1300 36 27 87 (local call cost).

Know warning signs of heart attack and what to do:

- Tightness, fullness, pressure, squeezing, heaviness or pain in your chest, neck, jaw, throat, shoulders, arms or back.
- You may also have difficulty breathing, or have a cold sweat or feel dizzy or light headed or feel like vomiting (or actually vomit).
- If you have heart attack warning signs that are severe, get worse or last for 10 minutes even if they are mild, call triple zero (000). Every minute counts.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SPIRACTIN.

Like other medicines, SPIRACTIN may cause unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

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:

- vomiting, feeling sick (nausea)
- stomach cramps or pain
- diarrhoea
- headache
- drowsiness, lethargy or generally feeling unwell
- skin rash, itchiness, hives
- unsteadiness when walking
- leg cramps
- hair loss or thinning
- excessive hair growth
- menstrual problems in women
- post-menopausal bleeding
- breast pain
- change in sex drive
- impotence (inability to get or maintain an erection in men)
- breast enlargement in men. This normally goes away when SPIRACTIN is stopped. In rare instances some breast enlargement may persist.

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

- mental confusion or dizziness
- frequent infection such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal.
- breast lumps and breast cancer have been reported in patients taking SPIRACTIN although SPIRACTIN has not been shown to cause breast cancer.

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

If any of the following happen, tell your doctor immediately or go

to Accident and Emergency at your nearest hospital:

- yellow skin and eyes (jaundice). SPIRACTIN can cause impairment of liver function.
- stomach bleeding, ulcers or gastritis (inflammation of the stomach)
- vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- irregular heartbeat, tingling sensation, paralysis or difficulty in breathing, which may be symptoms of raised potassium levels in your blood

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.

Other side effects not listed above may also occur in some patients.

After taking SPIRACTIN

Storage

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 in the car or on a window sill.

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 this medicine, or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

SPIRACTIN comes in 2 strengths of tablets:

- SPIRACTIN 25 - round, pale orange, peppermint flavoured tablet, marked SP/1 and a Greek alpha symbol
- SPIRACTIN 100 - round, pale orange, peppermint flavoured tablet, marked SP/2 and a Greek alpha symbol.

Each bottle contains 100 tablets.

Ingredients

The active ingredient in SPIRACTIN is spironolactone

- each SPIRACTIN 25 tablet contains 25 mg of spironolactone
- each SPIRACTIN 100 tablet contains 100 mg of spironolactone.

The tablets also contain:

- lactose monohydrate
- microcrystalline cellulose
- maize starch
- sodium starch glycollate
- purified talc
- magnesium stearate
- polysorbate 80
- povidone
- quinoline yellow
- erythrosine
- sunset yellow FCF
- peppermint oil.

SPIRACTIN contains sugars as lactose and trace quantities of galactose and sulfites.

Manufacturer

SPIRACTIN is made in Australia
by:

Alphapharm Pty Ltd
trading as Viatris

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

Australian registration numbers:

SPIRACTIN 25 - AUST R 46689

SPIRACTIN 100 - AUST R 46691

SPIRACTIN is a Viatris company
trade mark.

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