

SPIRONOLACTONE VIATRIS

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using SPIRONOLACTONE VIATRIS?

SPIRONOLACTONE VIATRIS contains the active ingredient spironolactone. SPIRONOLACTONE VIATRIS is used to treat essential hypertension, oedematous disorders, primary aldosteronism, malignant hypertension, low potassium and hirsutism.

For more information, see Section [1. Why am I using SPIRONOLACTONE VIATRIS?](#) in the full CMI.

2. What should I know before I use SPIRONOLACTONE VIATRIS?

Do not use if you have ever had an allergic reaction to spironolactone or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use SPIRONOLACTONE VIATRIS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SPIRONOLACTONE VIATRIS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use SPIRONOLACTONE VIATRIS?

Daily doses of SPIRONOLACTONE VIATRIS in adults can range from 25 mg to 400 mg. Depending on the dose and your condition, SPIRONOLACTONE VIATRIS 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 VIATRIS every day or in repeating cycles with a break in between.

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

More instructions can be found in Section [4. How do I use SPIRONOLACTONE VIATRIS?](#) in the full CMI.

5. What should I know while using SPIRONOLACTONE VIATRIS?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor or dentist you visit that you are using SPIRONOLACTONE VIATRIS.• If you are about to have any blood tests, tell your doctor that you are taking this medicine.• Tell your doctor if you are taking other types of medicines to treat high blood pressure or to prevent blood clots.• Tell your doctor immediately if you become pregnant while you are taking this medicine. |
| Things you should not do | <ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not take with potassium sparing diuretics.• Do not take potassium supplements or use salt substitutes that contain potassium.• Do not consume a diet rich in potassium. |
| Driving or using machines | <ul style="list-style-type: none">• Do not drive or operate machinery until you know how SPIRONOLACTONE VIATRIS affects you. |
| Looking after your medicine | <ul style="list-style-type: none">• Keep SPIRONOLACTONE VIATRIS in a cool dry place where the temperature stays below 30°C. |

For more information, see Section [5. What should I know while using SPIRONOLACTONE VIATRIS?](#) in the full CMI.

6. Are there any side effects?

Some common side effects include cramping, diarrhoea, nausea, vomiting, drowsiness, lethargy, generally feeling unwell, skin rash, itchiness, peeling skin, skin redness, fever, sore throat, unusual hair loss or thinning or excessive hair growth.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

SPIRONOLACTONE VIATRIS

Active ingredient: *spironolactone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SPIRONOLACTONE VIATRIS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SPIRONOLACTONE VIATRIS.**

Where to find information in this leaflet:

1. [Why am I using SPIRONOLACTONE VIATRIS?](#)
2. [What should I know before I use SPIRONOLACTONE VIATRIS?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use SPIRONOLACTONE VIATRIS?](#)
5. [What should I know while using SPIRONOLACTONE VIATRIS?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using SPIRONOLACTONE VIATRIS?

SPIRONOLACTONE VIATRIS contains the active ingredient **spironolactone**. SPIRONOLACTONE VIATRIS 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. SPIRONOLACTONE VIATRIS works against the effects of aldosterone and helps to maintain normal levels of potassium in the blood by retaining potassium in the body.

SPIRONOLACTONE VIATRIS 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. 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 VIATRIS 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 VIATRIS 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 facial or body hair in women).

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. SPIRONOLACTONE VIATRIS has a moderate ability to act against testosterone (anti-androgenic effect). Because of this, SPIRONOLACTONE VIATRIS 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 SPIRONOLACTONE VIATRIS is used to treat hirsutism. This is because aldosterone levels are not normally high in patients with hirsutism.

There is no evidence that SPIRONOLACTONE VIATRIS is addictive.

2. What should I know before I use SPIRONOLACTONE VIATRIS?

Warnings

Do not use SPIRONOLACTONE VIATRIS if:

- you are allergic to spironolactone, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Some of the symptoms of an allergic reaction may include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin.
- you are pregnant or think you might be pregnant
SPIRONOLACTONE VIATRIS 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 have severe kidney disease or are not passing urine.
- you have hyperkalaemia (high levels of potassium in the blood).
- you have Addison's disease (a condition where the adrenal glands do not work properly).
- you are taking eplerenone, a potassium sparing diuretic used to treat heart failure or high blood pressure.

- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- are allergic to any other medicines, foods, preservatives or dyes.
- have or have had any of the following medical conditions.
 - o liver problems
 - o kidney problems
 - o severe heart failure.
- take any medicines for any other conditions, including:
 - o potassium supplements
 - o potassium containing salt substitutes
 - o potassium sparing diuretics
 - o other medicines for high blood pressure.
- Tell your doctor if you plan to have surgery.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Women of child-bearing age

The safety of SPIRONOLACTONE VIATRIS 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.

3. What if I am taking other medicines?

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

Some medicines may interfere with SPIRONOLACTONE VIATRIS and affect how it works, including:

- 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
- medicines to prevent blood clots including aspirin
- potassium supplements 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
- non-steroidal anti-inflammatory medicines (NSAIDs) or other medicines which are 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
- abiraterone treatment in prostate cancer patients.
- Lithium, a medicine used to treat depression.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SPIRONOLACTONE VIATRIS.

4. How do I use SPIRONOLACTONE VIATRIS?

How much to take

- daily doses of SPIRONOLACTONE VIATRIS in adults can range from 25 mg to 400 mg
- doses of SPIRONOLACTONE VIATRIS in children are measured according to body weight and will be calculated by your doctor
- follow the instructions provided and use SPIRONOLACTONE VIATRIS until your doctor tells you to stop.

When to take SPIRONOLACTONE VIATRIS

- depending on the dose and your condition, SPIRONOLACTONE VIATRIS may be taken once a day or divided into separate doses
- take SPIRONOLACTONE VIATRIS with or immediately after food
- in the treatment of hirsutism (excess body hair) in females, your doctor may tell you to take SPIRONOLACTONE VIATRIS every day or in repeating cycles with a break in between.

If you forget to use SPIRONOLACTONE VIATRIS

SPIRONOLACTONE VIATRIS should be used regularly at the same time each day.

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 you missed.

If you use too much SPIRONOLACTONE VIATRIS

If you think that you have used too much SPIRONOLACTONE VIATRIS, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Overdose may cause nausea and vomiting. Sometimes, drowsiness, mental confusion, rash, diarrhoea or dehydration may occur.

5. What should I know while using SPIRONOLACTONE VIATRIS?

Things you should do

- Take SPIRONOLACTONE VIATRIS exactly as your doctor has prescribed.
- If you are about to have any blood tests tell your doctor that you are taking SPIRONOLACTONE VIATRIS.

SPIRONOLACTONE VIATRIS may interfere with the results of some tests.

- Tell your doctor if you are taking other types of medicines to treat high blood pressure.
- Tell your doctor if you are taking medicines to prevent blood clots.
- Tell your doctor immediately if you become pregnant while you are taking SPIRONOLACTONE VIATRIS.

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

Examples of adequate contraception are oral contraceptives ("the Pill") or intra-uterine devices (IUDs).

- Stop taking SPIRONOLACTONE VIATRIS if you become pregnant or you think you may be pregnant.
- Go to your doctor regularly for a 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 VIATRIS if your blood is high in potassium or if your kidneys are not working properly.

Call your doctor straight away if you:

- become pregnant while you are taking SPIRONOLACTONE VIATRIS.

Remind any doctor or dentist you visit that you are using SPIRONOLACTONE VIATRIS. This is especially important if you are going to receive an anaesthetic agent while being treated with SPIRONOLACTONE VIATRIS.

Things you should not do

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SPIRONOLACTONE VIATRIS affects you.

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

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.

Looking after your medicine

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

- Keep SPIRONOLACTONE VIATRIS in a cool dry place where the temperature stays below 30°C.

Follow the instructions in the label on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

6. Are there any 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

| Common side effects | What to do |
|--|---|
| <ul style="list-style-type: none"> • Cramps or diarrhoea • nausea or vomiting • drowsiness, lethargy or generally feeling unwell • skin rash, itchiness, hives • peeling skin or skin redness • fever or sore throat • unusual hair loss or thinning • excessive hair growth | <p>Speak to your doctor or pharmacist if you have any of these common side effects and they worry you.</p> |

Serious side effects

| Serious side effects | What to do |
|---|---|
| <ul style="list-style-type: none"> • 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 SPIRONOLACTONE VIATRIS. • breast enlargement Breast enlargement may occur in men taking SPIRONOLACTONE VIATRIS. This normally goes away when SPIRONOLACTONE VIATRIS is stopped. In rare instances some breast enlargement may persist. | <p>The serious side effects may require medical attention.</p> |

| Serious side effects | What to do |
|--|------------|
| <ul style="list-style-type: none"> • breast lumps Breast lumps and breast cancer have been reported in patients taking SPIRONOLACTONE VIATRIS although SPIRONOLACTONE VIATRIS 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 | |

Very serious side effects

| Very serious side effects | What to do |
|--|--|
| <ul style="list-style-type: none"> • yellow skin and eyes (jaundice). SPIRONOLACTONE VIATRIS 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 | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What SPIRONOLACTONE VIATRIS contains

| | |
|---|---|
| Active ingredient (main ingredient) | SPIRONOLACTONE VIATRIS 25 tablets contain 25 mg spironolactone SPIRONOLACTONE VIATRIS 100 tablets contain 100 mg spironolactone |
| Other ingredients (inactive ingredients) | lactose monohydrate microcrystalline cellulose maize starch sodium starch glycollate purified talc magnesium stearate polysorbate 80 povidone quinoline yellow aluminium lake erythrosine aluminium lake sunset yellow FCF aluminium lake peppermint oil |
| Potential allergens | trace quantities of sulfites trace quantities of galactose sugars as lactose |

Do not take this medicine if you are allergic to any of these ingredients.

What SPIRONOLACTONE VIATRIS looks like

SPIRONOLACTONE VIATRIS 25 is 7 mm pale orange, normal convex, peppermint flavoured tablet marked "SP" breakline "1" on one side, " alpha" symbol on the reverse. (AUST R 338091).

SPIRONOLACTONE VIATRIS 100 is 11 mm pale orange, normal convex, peppermint flavoured tablet marked "SP" breakline "2" on one side, "alpha" symbol on the reverse (AUST R 338092).

Who distributes SPIRONOLACTONE VIATRIS

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

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