

Aldactone®

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 Aldactone?

Aldactone contains the active ingredient spironolactone. Aldactone 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 Aldactone?](#) in the full CMI.

2. What should I know before I use Aldactone?

Do not use if you have ever had an allergic reaction to Aldactone 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 Aldactone?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Aldactone 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 Aldactone?

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

Doses of Aldactone 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 Aldactone?](#) in the full CMI.

5. What should I know while using Aldactone?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or dentist you visit that you are using Aldactone.• If you are about to have any blood tests, tell your doctor that you are taking Aldactone.• 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 Aldactone.
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.

	<ul style="list-style-type: none"> • 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 Aldactone affects you.
Looking after your medicine	<ul style="list-style-type: none"> • Keep Aldactone in a cool dry place where the temperature stays below 30°C.

For more information, see Section [5. What should I know while using Aldactone?](#) 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.

Aldactone® (al-dak-tone)

Active ingredient(s): spironolactone (spur-ron-o-lack-tone)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Aldactone. **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 Aldactone.**

Where to find information in this leaflet:

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

1. Why am I using Aldactone?

Aldactone contains the active ingredient spironolactone. Aldactone 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. Aldactone works against the effects of aldosterone.

Aldactone 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.

Aldactone 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)

Aldactone 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).

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

2. What should I know before I use Aldactone?

Warnings

Do not use Aldactone if:

1. 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.

2. you are pregnant or think you might be pregnant

Aldactone should not be used during pregnancy due to possible effects on the developing baby (fetus).

3. you are breast feeding

The drug may appear in the breast milk and be passed to the infant.

4. you have severe kidney disease or are not passing urine

5. you have hyperkalaemia (high levels of potassium in the blood)

6. you have Addison's disease (a condition where the adrenal glands do not work properly).

7. you are taking eplerenone, a potassium sparing diuretic used to treat heart failure or high blood pressure
8. 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:

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

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 Aldactone 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 and Aldactone may interfere with each other, including:

- 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 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 medicines (NSAIDs) 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
- 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 Aldactone.

4. How do I use Aldactone?

How much to take

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

When to take Aldactone

- depending on the dose and your condition, Aldactone 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 Aldactone

every day or in repeating cycles with a break in between.

If you forget to use Aldactone

Aldactone 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.

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

If you use too much Aldactone

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

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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 Aldactone?

Things you should do

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

Aldactone 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 if you become pregnant while you are taking Aldactone

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

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

- Stop taking Aldactone 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 Aldactone 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 Aldactone.

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

Things you should not do

- Do not stop using this medicine suddenly.
- 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 Aldactone, 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 Aldactone affects you.

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

Looking after your medicine

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

Follow the instructions on the carton 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.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

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.

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">• 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

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 Aldactone. ● breast enlargement Breast enlargement may occur in men taking Aldactone. This normally goes away when Aldactone is stopped. In rare instances some breast enlargement may persist. ● breast lumps Breast lumps and breast cancer have been reported in patients taking Aldactone although Aldactone has not been shown to cause breast cancer. 	<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>

Serious side effects	What to do
<ul style="list-style-type: none"> • 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 <p>May be due to hyperkalaemia (high levels of potassium in the blood) that is very serious.</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 Aldactone contains

Active ingredient (main ingredient)	Aldactone 25 mg tablets contain 25 mg spironolactone Aldactone 100 mg tablets contain 100 mg spironolactone
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Other ingredients (inactive ingredients)	calcium sulfate dihydrate maize starch povidone magnesium stearate hypromellose macrogol 400 peppermint flavour Opaspray yellow
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Do not take this medicine if you are allergic to any of these ingredients.

What Aldactone looks like

Aldactone 25 mg - round, biconvex, buff coloured, peppermint flavoured, film coated tablets; stamped SEARLE over 39 on one side and unmarked on the other side.

AUST R 68953

Aldactone 100 mg - round, biconvex, buff coloured, peppermint flavoured, film coated tablets; stamped SEARLE over 134 on one side and unmarked on the other side.

AUST R 68954

The tablets are available in blister packs of 100 tablets.

Who distributes Aldactone

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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