LEAFLET: INFORMATION FOR THE USER
Spironolactone Aurobindo 25 mg, tablets
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Spironolactone Aurobindo 100 mg, tablets
spironolactone

Read the entire leaflet carefully before you start using this medicine, because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm others, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

1. What is Spironolactone Aurobindo and what is it used for?

Spironolactone Aurobindo belongs to the group of so-called potassium-sparing diuretics. It counteracts the action of aldosterone. Aldosterone is a natural substance in the body that retains fluid. Spironolactone reduces the amount of fluid in the body by increasing urine production. Spironolactone also has a blood pressure-lowering effect.

This medicine is intended for patients with:
- fluid retention in body tissues due to heart conditions, especially in difficult-to-treat cases
- high blood pressure, as a supplement to a salt-free diet and diuretics when these alone are not sufficiently effective
- certain kidney disorders, when diuretics have insufficient effect or cannot be used
- fluid retention in body tissues and abdominal cavity due to liver disorders.

Spironolactone Aurobindo is also used before surgery, treatment, or diagnosis of Conn's disease (a condition where too much aldosterone is produced due to a tumor or enlargement of the adrenal cortex).

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?
You should not use this medicine if you have certain conditions. These conditions, which can be recognized by your doctor, are:

You are allergic to any of the ingredients in this medicine. These ingredients can be found in section 6;
A severe kidney dysfunction or a severe reduction in kidney function;
Sudden onset or worsening of kidney disease, possibly in combination with (almost) complete lack of urine production;
Too high a level of potassium or too low a level of sodium in the blood;
Addison's disease;
Simultaneous use of other potassium-sparing diuretics.

Spironolactone should not be given to children with moderate to severe kidney disease.

When should you be extra careful with this medicine?
Contact your doctor or pharmacist before taking this medicine:
if you have a kidney disease. This is especially important for children with high blood pressure;
if you have a liver disease;
if you are an elderly patient and/or have a blockage in the parts of the body that absorb and excrete urine, or have a disease that can lead to electrolyte disturbances (salts such as sodium, potassium, calcium, chloride, and bicarbonate in the blood and other body fluids);
if you have severe heart failure. Once you are treated with spironolactone, your doctor will monitor the potassium level in your blood due to the risk of too much potassium in your blood (hyperkalemia), which can be fatal;
if you have impaired kidney function or kidney failure, as the potassium level in your blood can rise significantly. This can affect the functioning of your heart. In extreme cases, this can be fatal.

Your doctor or nurse will regularly perform blood tests to check the fluid levels and electrolytes (potassium and sodium).
This is especially important in the elderly and patients with impaired kidney function.

Treatment with spironolactone can lead to higher levels of potassium and blood urea nitrogen (a marker for liver and kidney problems) and a decrease in sodium levels, especially in the elderly and/or patients with heart, kidney, or liver problems. A high potassium level (hyperkalemia) can be fatal in extreme cases.

Concurrent administration of spironolactone and certain medications, e.g., trimethoprim-sulfamethoxazole (co-trimoxazole), potassium supplements, and potassium-rich foods, can lead to severe hyperkalemia (the amount of potassium in your blood is too high).

The symptoms of severe hyperkalemia include:
muscle cramps
irregular heartbeat
diarrhea
nausea
dizziness
headache.

Are you experiencing the above complaints? Contact your doctor. He can perform additional checks and adjust the treatment if necessary.

Are you taking any other medications?
Are you taking any other medications besides Spironolactone Aurobindo, have you done so recently, or is there a possibility that you will take other medications in the near future? Tell your doctor or pharmacist.

Some medications can enhance or weaken each other's effects or should not be used simultaneously for other reasons.

Medications known to affect the action of spironolactone or whose action can be affected by spironolactone, with an effect on the amount of potassium in your blood, are:

potassium-sparing diuretics and aldosterone blockers, angiotensin-converting enzyme inhibitors (ACE inhibitors), angiotensin II antagonists (the risk of too much potassium in the blood may be increased, especially with impaired kidney function. Your doctor should dose carefully and monitor you closely. Concurrent use should be avoided in severe renal impairment).
ciclosporin (certain medication for transplantation and treatment of autoimmune diseases): possible increase in blood potassium levels.
corticosteroids and ACTH: reduction of the blood pressure-lowering effect of spironolactone.
colestyramine (certain medication for high cholesterol): may reduce the diuretic effect of spironolactone.
ammonium chloride may increase the risk of elevated blood potassium levels and acidosis.
certain antibiotics: trimethoprim and trimethoprim-sulfamethoxazole. These drugs increase the risk of elevated blood potassium levels.

Other medications that may interact:

Spironolactone Aurobindo can be used concurrently with other diuretic and blood pressure-lowering medications: sometimes it will be necessary to reduce their dose.
noradrenaline: if used during anesthesia; the vasoconstrictive effect of noradrenaline may be reduced.
NSAIDs such as diclofenac, ibuprofen, and naproxen (group of painkillers with anti-inflammatory and antipyretic effects); the effect of spironolactone can decrease and may promote the occurrence of acute renal failure in dehydrated patients.
salicylates, such as acetylsalicylic acid (painkillers); the effect of spironolactone may decrease.
heparin (medication that prevents blood clot formation); the effect of spironolactone may be enhanced.
anticoagulant medications; the effect of the anticoagulant medications may decrease.
digoxin (medication that enhances the heart's pumping power, cardiac glycoside); the effect of digoxin may be enhanced.
lithium (certain medication for depression): possible increased lithium concentration in the blood.

Tell your doctor if you are using abiraterone for the treatment of prostate cancer. Use in combination with abiraterone is not recommended.

Tell your doctor if you are using mitotane for the treatment of malignant adrenal tumors. This medication should not be used in combination with mitotane.

What should you pay attention to with food and drink?
You should be careful with foods rich in potassium and salt substitutes containing potassium due to the risk of increasing the amount of potassium in the blood (hyperkalemia, potentially fatal) especially in case of prior kidney function impairment.

Pregnancy, breastfeeding and fertility
Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Pregnancy
There is insufficient data on the use of spironolactone during pregnancy in humans to assess potential harm. Spironolactone should not be used during pregnancy.

Breastfeeding
Spironolactone should not be used if you are breastfeeding. You should discuss the use of Spironolactone with your doctor, who will advise you to consider an alternative way of feeding your baby while taking this medicine.

Fertility Women:
Spironolactone can cause irregular menstruation.
Men:
Spironolactone can cause impotence.

Driving and using machines
This medicine can cause drowsiness, dizziness, confusion, and headache as side effects. You should take this into account when participating in traffic and operating (dangerous) machines and be extra cautious.

Spironolactone Aurobindo contains lactose
If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

Instructions for use
The tablets are best taken during meals with a generous amount of water (half a glass). If you use more than 100 mg per day, it is best to divide this over multiple intake moments. In case of a single dose, preferably at breakfast.

Dosage
Your doctor has determined a dosage. In general, the dosages below provide sufficient results. In the elderly, it is recommended to start with the lowest possible dose. Caution is needed in case of impaired kidney function.

Increased blood pressure
The daily dose is usually 50 mg to 100 mg per day in adults. The daily dose can be taken in a single intake or spread throughout the day.
The treatment must last at least 2 weeks, as the expected effect does not always occur immediately. Only after 2 weeks may the dose be increased by the doctor, if necessary.

Fluid retention in tissues (edema) due to heart conditions
The daily dose can be taken in a single intake or spread throughout the day.

The daily recommended starting dose is 100 mg per day, in a single intake or spread throughout the day. This dose can vary from 25 mg to 200 mg per day. The maintenance dose is determined individually.

In severe heart conditions in combination with standard treatment, the recommended starting dose is 25 mg per day. If necessary, and if you tolerate the single daily dose of 25 mg well, the dose can be increased to 50 mg once a day.
If you do not tolerate the single daily dose of 25 mg well, the dose can be reduced to 25 mg every other day.

Fluid retention in tissues (edema) due to liver cirrhosis:
The doctor will determine the dose on a case-by-case basis after the amount of sodium and potassium in your urine has been determined.

Kidney disorders:
The daily dose is usually 100 mg to 200 mg per day.

Surgery, diagnosis, and treatment of Conn's disease:
Diagnosis and treatment of the disease:
Long-term test: 100-150 mg per day (=24 hours) and then before the surgery: 100-150 mg per day, 3-5 weeks before the surgery.
Short-term test: 400 mg per day is administered for 4 days.

Use in children
To facilitate intake, the tablet can be crushed or broken in a glass of water.

The number of Spironolactone Aurobindo tablets you should give a child depends on the child's body weight. Your doctor will determine the number of tablets to be administered. The daily dosage in children is usually 3 mg per kg of body weight per day (=24 hours).

Have you taken too much of this medicine?
If too much is taken, the following symptoms may occur: nausea, vomiting, and (more rarely) diarrhea, drowsiness, (mental) confusion, skin rash (redness of the skin), and dehydration. If you suspect an overdose, you must immediately alert a doctor.

Did you forget to take this medicine?
If you forgot to take a dose, you should do so as soon as possible.
When the time until the next dose is shorter than the time until the missed dose, you do not need to do anything. It is better to skip one dose. Do not take a double dose to make up for a missed dose.

If you stop taking this medicine
Never change the dosage yourself and never stop the treatment yourself, even if you have complaints. First consult your doctor. He/she can tell you if you can stop and how best to do so.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can cause side effects, although not everyone gets them.

Contact your doctor immediately if you experience any of the following complaints after using this medicine. Although they are very rare, the symptoms can be serious:

- itching and blistering of the skin around the lips and on the rest of the body, red or purple skin rash that spreads and shows blistering (Stevens-Johnson syndrome);
- detachment of the upper skin layer from the underlying skin layers, over the entire body (toxic epidermal necrolysis – TEN);
- skin rash, fever, and swelling (which may be symptoms of something more serious, namely: drug reaction with eosinophilia and systemic symptoms (DRESS));
- yellow skin and eyes (spironolactone can cause reduced liver function);
- irregular heartbeat that can be fatal, tingling sensation, paralysis (loss of muscle function), or breathing difficulties. These may be symptoms of increased potassium levels in your blood. Your doctor will regularly perform blood tests to check potassium levels and other electrolyte levels. If necessary, he or she may discontinue your treatment.

The side effects mentioned below are categorized by frequency as follows:

Very common: occurs in more than 1 in 10 users
Gynecomastia (breast formation), breast pain (male).

Common: occurs in less than 1 in 10 users
Too much potassium in the blood (hyperkalemia), being confused (confusion), dizziness, nausea, itching, rash, muscle cramps, sudden reduced kidney function (acute renal failure), feeling sick or feeling unwell (malaise).

Sometimes: occurs in less than 1 in 100 users
Confusion, headache, drowsiness, dizziness, benign breast tumor (man), electrolyte disturbances (the amount of certain salts in your body such as potassium, sodium), coordination problems (ataxia), abnormal liver function, skin rash with pink bumps and severe itching (hives or welts).

Very rare: occurs in less than 1 in 10,000 users
Liver poisoning (hepatotoxicity), liver inflammation (hepatitis), skin rash with severe itching (hives) and formation of bumps (welts), skin rash with spots and nodules (maculopapular rash) or skin rash consisting of red spots (erythematous eruption).

Unknown: based on the available data, the frequency cannot be determined
Very serious blood disorder with sudden high fever, severe sore throat and mouth ulcers (agranulocytosis), low blood pressure, dehydration. Too few white blood cells in your blood (leukopenia), few blood platelets in your blood (thrombocytopenia). Too little sodium in the blood (hyponatremia), especially during intensive treatment in combination with thiazide diuretics, blood acidification (metabolic acidosis). Stomach bleeding, ulcers, diarrhea, nausea, vomiting and leg cramps. A severe illness usually caused by a drug or infection (Stevens-Johnson syndrome). The disease starts with a skin rash and blisters. The blisters can be in the mouth, nose, vagina, tip of the penis, a severe skin rash (toxic epidermal necrolysis). You may experience fever, blisters, peeling skin, skin detachment. Rash with severe skin inflammation due to an allergy to a drug (DRESS syndrome) and too many white blood cells (eosinophilia). White blood cells protect the body against diseases. Hair disease causing bald patches on your head (alopecia areata) or excessive unwanted hair growth, in areas where there is usually only light hair (hypertrichosis). Pemphigoid (condition where fluid-filled blisters occur on the skin).
Men: impotence, reduced sex drive (libido).
Women: excessive hair growth (hirsutism), absence of menstruation (amenorrhea), irregular menstruations (irregular menses), menstruations with large, usually irregular, intervals (oligomenorrhea), painful breasts and voice deepening.

Reporting side effects
If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How do you store this medicine?

Keep out of the sight and reach of children.

Store below 25°C in the original packaging to protect against moisture and light (bathroom and kitchen are therefore unsuitable).

Do not use this medicine after the expiry date. It can be found on the packaging and on the blister strips after "EXP" (= not to be used after). It states a month and a year. The last day of that month is the expiry date.
You can return any unused tablets to your pharmacy for destruction.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

The active substance is spironolactone. Each tablet contains 25, 50, and 100 mg of spironolactone, respectively.

The other substances (excipients) in this medicine are: lactose, maize starch, calcium phosphate, povidone, talc, magnesium stearate, peppermint oil, silicon dioxide, hydroxypropylmethylcellulose, polyethylene glycol, titanium dioxide (E171), shellac, white beeswax, and carnauba wax.

What does Spironolactone Aurobindo look like and what is in a package?
Ensure you are using the correct medicine:
25 mg tablets: round, biconvex, white tablets with a diameter of 8 mm.
50 mg tablets: round, biconvex, white tablets with a diameter of 10 mm.
100 mg tablets: round, biconvex, white tablets with a diameter of 11 mm.

The tablets are available in blister packs of 20, 30, or 50 pieces and bottle packaging of 100 and 250 pieces.

Marketing authorization holder and manufacturer

Marketing authorization holder
Aurobindo Pharma B.V.
Baarnsche Dijk 1
3741 LN Baarn
Netherlands

Manufacturer
Aurobindo Pharma B.V.
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The medicine is registered under:
RVG 24686 Spironolactone Aurobindo 25 mg, tablets
RVG 24687 Spironolactone Aurobindo 50 mg, tablets
RVG 24688 Spironolactone Aurobindo 100 mg, tablets

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