

Patient Information Leaflet

Amiloride 5mg/5ml Oral Solution

- Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed only for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Amiloride is and what it is used for
2. What do you need to know before you take Amiloride
3. How to take Amiloride
4. Possible side effects
5. How to store Amiloride
6. Contents of the pack and other information

1. What Amiloride is and what it is used for

The name of your medicine is Amiloride Oral Solution (called Amiloride in this leaflet). It contains amiloride hydrochloride. This belongs to a group of medicines called diuretics (water tablets).

Amiloride can be used to stop the build up of extra water in your body. It does this without loss of potassium from your body. This extra water can lead to high blood pressure, heart problems (congestive heart failure) and liver problems (hepatic cirrhosis).

It works by helping you to pass more water (urine) than you usually do.

2. What do you need to know before you take Amiloride

Do not take Amiloride and tell your doctor if:

- You are allergic (hypersensitive) to amiloride or any other ingredients in this liquid (listed in Section 6 below)
Signs of an allergic reaction include: a rash, itching or shortness of breath
- You have an illness called 'Addison's Disease'. This is when your adrenal glands are not working properly. It can cause weakness, tiredness, weight loss and low blood pressure
- You have kidney problems. This includes those caused by diabetes
- Your doctor has told you that you have high potassium levels
- You are not passing any water (urine)
- The person taking the medicine is a child under 18 years old

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor before taking Amiloride.

Take special care with Amiloride

Before you take Amiloride tell your doctor if:

- You have diabetes
- You have liver problems
- Your doctor has told you that you have too much acid in your blood. This can be caused by diabetes or heart or lung disease

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Amiloride.

Tests

Tell your doctor or nurse you are taking Amiloride if you are going to have a glucose tolerance test. This is because this medicine can affect the results. You will need to stop taking this medicine three days before your test.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Amiloride can affect the way some other medicines work. Also, some medicines can affect the way Amiloride works.

In particular, tell your doctor if you are taking any of the following:

- Lithium - used for depression
- Medicines used for heart failure (such as captopril, lisinopril, candesartan)
- Diuretics (water tablets) such as furosemide and spironolactone
- Medicines or supplements containing potassium (including table salt substitutes)
- Trilostane – used for ‘Cushings syndrome’ or breast cancer
- Ciclosporin or tacrolimus – used after transplants to stop the rejection of organs
- Non-steroidal anti-inflammatory (NSAID) medicines such as diclofenac and ibuprofen. Your doctor may want to carry out tests on your kidneys and the level of potassium in your blood, especially if you are an older person
- Chlorpropamide – used to treat diabetes.

This medicine does not cause loss of potassium from your body as other water tablets do. Therefore, it is not necessary for you to get extra potassium in your diet or take supplements. Too much potassium could even be harmful.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, planning to become pregnant or are breast-feeding.

Driving and using machines

Amiloride is not likely to affect you being able to drive or use any tools or machines.

Important information about what is in Amiloride

This medicine contains:

- Methyl and propyl parahydroxybenzoates. These may cause an allergic reaction. This allergy may happen some time after starting the medicine.
- Liquid maltitol (E965). If your doctor has told you that you cannot tolerate some sugars, see your doctor before taking this medicine.
- Propylene glycol (E1520) 103.5mg in each 5ml. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.
- Ethanol. This medicine contains 3.7 mg of alcohol (ethanol) in each 5 ml. The amount in 5 ml of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to take Amiloride

Take this medicine as your doctor or pharmacist has told you. Look on the label and ask the doctor or pharmacist if you are not sure.

Taking this medicine

- This medicine contains 5mg of amiloride hydrochloride in each 5ml
- Take this medicine by mouth
- If you are taking a single dose, take it in the morning
- If you are taking more than one dose, take the last dose before 6pm. Unless your doctor tells you otherwise
- Plan your doses so that they do not affect your personal activities and sleep
- Your doctor will check your progress regularly to make sure the medicine is working properly

Adults

The usual doses for adults are:

Amiloride taken alone

- 10mg each day
- This may be increased to 20mg each day

Amiloride taken with other diuretics

High blood pressure

- 2.5mg with the diuretic each day
- This may be increased to 5mg each day

Congestive heart failure

- 2.5mg with the diuretic
- This may be increased to 10mg each day

Cirrhosis of the liver

- 5mg with the diuretic each day
- This may be increased to 10mg each day

Children

This medicine is not usually given to children under the age of 18.

Older People

Your doctor will decide how much Amiloride to give you.

If you take more Amiloride than you should

Talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken

If you forget to take Amiloride

Do not take a double dose (two doses at the same time) to make up for a forgotten dose. Take your next dose as soon as you remember, then go on as before. However, if it is nearly time for the next dose, skip the missed dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Amiloride can cause side effects although not everybody gets them.

If you have an allergic reaction to Amiloride see a doctor straight away

An allergic reaction may include:

- Any kind of skin rash, flaking skin, boils or sore lips and mouth
- Sudden wheezing, fluttering or tightness of the chest or collapse.

If you get any of the following side effects, stop taking Amiloride and see your doctor as soon as possible:

- Chest pain including angina pain
- Unusual heart beats
- Bleeding in the stomach. Signs include passing black stools
- Yellowing of the skin and the whites of the eyes (jaundice)
- Feeling dizzy, particularly when standing up
- Disease of the brain (encephalopathy)
- Feeling depressed
- Difficulty in breathing
- Problems with your sight and increased pressure in the eye
- Worsening of the effects of a stomach ulcer
- Pain while passing urine and spasms of the bladder
- Changes in the results of blood tests. These include changes in the way your liver is working, changes in red or white blood cell levels or changes in sodium or potassium levels.

Tell your doctor if you get any of these side effects:

- Headache
- Feeling sick or being sick
- Diarrhoea or constipation
- Stomach pain and wind
- Feeling weak or tired
- Pain in the back, neck, shoulder, fingers, toes or joints
- Painful swelling of the joints (gout)
- Skin rash, itching
- Feeling thirsty and dry mouth
- Loss of appetite
- Hair loss
- Muscle cramps, pins and needles
- Feeling nervous or confused
- Unable to sleep or feeling sleepy
- Coughing, blocked nose
- Ringing in the ears

- Changes in your sexual drive and function
- Shaking
- Increase in the number of times and the amount of water (urine) you pass. This may be because your bladder is not emptying completely or due to the medicine.

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in the leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Amiloride

- Keep out of the sight and reach of children
- Do not store above 25°C
- Do not use after the expiry date which is stated on the label and carton (Exp: month, year)
- The expiry date refers to the last day of that month
- Do not use Amiloride if you notice a change in the appearance or smell of the medicine. Talk to your pharmacist
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

6. Contents of the pack and other information

What Amiloride contains

- The active ingredient is amiloride hydrochloride
- The other ingredients are citric acid (E330), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), propylene glycol (E1520), vanillin, compound orange spirit (contains ethanol), liquid maltitol (E965) and purified water

What Amiloride looks like and contents of the pack

A colourless to pale yellow solution with an odour of vanilla.

It comes in a brown glass bottle holding 150ml of solution.

Marketing Authorisation Holder

Essential Pharma Ltd, 8a Crabtree Road, Egham, Surrey, TW20 8RN, UK.

Manufacturer

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

This leaflet was last revised in 06/2024