Pharmacode

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Amiloride Hydrochloride 5 mg Tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- **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 for you only.** Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

WHAT IS IN THIS LEAFLET

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1. WHAT AMILORIDE TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Amiloride Hydrochloride 5 mg Tablets (called Amiloride in this leaflet). Amiloride Tablets contain the active ingredient amiloride hydrochloride which belongs to a group of medicines known as diuretics (water tablets).

Amiloride can be used to stop the build up of excess water in your body. It does this by helping you pass more than you usually do, without the loss of potassium from the body.

Amiloride is mainly used together with other medicines that increase urine flow in order to conserve potassium.

Amiloride can be used in the treatment of:
- heart problems (congestive heart failure)
- high blood pressure (hypertension)
- fluid retention caused by liver problems (hepatic cirrhosis)

If you are not sure why you have been prescribed Amiloride, please ask your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AMILORIDE TABLETS

Do not take Amiloride if:
- you are allergic to amiloride hydrochloride, or any of the other ingredients of this medicine (listed in section 6)
- you have been told that you have high potassium levels (hyperkalaemia)
- you are taking any potassium containing medicines or supplements
- you are not passing any water (urine)
- you have severe kidney problems or kidney failure. This includes those caused by diabetes
- you have Addison's disease (a disease of the adrenal glands), which can cause weakness, tiredness, weight loss and low blood pressure
- 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.

Warnings and precautions
The presence of other medical problems may affect the use of this medicine. Talk to your doctor before taking Amiloride, if you:
- have kidney problems
- have liver problems
- have diabetes
- are elderly
- have too much acid in your blood. This can be caused by diabetes or heart or lung diseases

Children
Amiloride should not be used in children.

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

Tests and Operations
Regular blood and urine tests may be needed to monitor your electrolyte (e.g. potassium and sodium) levels.

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 and you will need to stop taking it three days before your test.

If you are going to have an operation where you will be given an anaesthetic, tell the doctor in charge that you are taking Amiloride.

Other medicines and Amiloride
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription and herbal medicines. This is because Amiloride can affect the way some medicines work, and some medicines can affect the way Amiloride works.

In particular, tell your doctor if you are taking any of the following:
- medicines to treat high blood pressure, such as captopril and enalapril (ACE inhibitors), doxazosin, prazosin (alpha-blockers), candesartan, losartan, valsartan (angiotensin-II receptor antagonists), aliskiren, clonidine, guanethidine, hydralazine, methyldopa, minoxidil, moxonidine or sodium nitroprusside
- medicines to treat high blood pressure or chest pain, such as atenolol, propranolol and sotalol (beta-blockers), amlodipine, nifedipine (calcium-channel blockers), glyceryl trinitrate, isosorbide mononitrate (nitrates), moxisylyte
- medicines to calm you down or help you sleep, such as diazepam or nitrazepam
- medicines known as Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) to treat pain and swelling, such as ibuprofen, indometacin, ketorolac
- some medicines for depression or mental health problems such as amitriptyline, dosulepin (tricyclic antidepressants), phenelzine, tranylcypromine (monoamine-oxidase inhibitors), chlorpromazine, trifluoperazine (phenothiazines), lithium
- some medicines to treat bacterial infections such as lymecycline, oxytetracycline (tetracyclines), amoxicillin, trimethoprim
- some medicines used in the treatment of diabetes, such as canagliflozin, chlorpropamide, diazoxide
- some medicines to treat Parkinson's disease, such as levodopa, co-beneldopa, co-careldopa
- ciclosporin or tacrolimus used to suppress the immune system and stop the rejection of organs after transplants
- cisplatin or aldesleukin used to treat types of cancer
- muscle relaxants such as baclofen or tizanidine
- hormones, such as oestrogens, for contraception or hormone replacement therapy
- trilostane used for treating Cushing's disease or breast cancer
- steroids, such as hydrocortisone or prednisolone, to treat swelling and allergies
- digoxin to treat heart failure
- alprostadil to treat erectile dysfunction
- carbamazepine to treat epilepsy
- pentamidine to treat microbial infections
- carbenoxolone to treat mouth ulcers
- total parenteral nutrition (intravenous administration of nutrients)
- antipsychotics such as amisulpride
- atomoxetine (used to treat ADHD)

Amiloride 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.

Amiloride with alcohol
- avoid alcohol whilst taking this medicine

Pregnancy and breast-feeding
Talk to your doctor before taking this medicine if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

Driving and using machines
If you feel dizzy while taking Amiloride do not drive or operate dangerous machinery.

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Amiloride Tablets contain lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE AMILORIDE TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The dose will depend on your condition and may need to be increased or decreased over time to control your symptoms. You will be prescribed the lowest dose necessary to control your symptoms. Do not take more of it, and do not take it more often or for a longer time than your doctor ordered.

The recommended dose is:

Adults:

Monotherapy:
Initially 10 mg each day, as a single or divided dose. This may be increased to a maximum of 20 mg per day.

Amiloride taken with other diuretics
Heart problems (congestive heart failure):
Initially 2.5 mg per day along with the other diuretic. This may be increased to a maximum of 10 mg each day.

High blood pressure (hypertension):
The usual 2.5 mg per day along with other diuretic each day. This may be increased to 10 mg each day.

Liver cirrhosis with swelling of the abdomen (ascites):
Initially 5 mg along with other diuretic each day. This may be increased to a maximum of 10 mg each day.

Use in Children:
The use of Amiloride is not recommended for children.

Older People:
Your doctor will decide how much Amiloride you should take. You may be given a lower dose depending on how well your kidneys are working, your blood electrolyte levels and your response to treatment.

If you take more Amiloride than you should
If you take more tablets than recommended contact your nearest doctor or hospital casualty department at once. Take any remaining tablets with you and keep in the original container or packaging so that they can be identified.

If you feel this medicine is not working as well after you have taken it for a short time (1-2 weeks) do not increase the dose, instead check with your doctor.

If you forget to take Amiloride
If you miss a dose, skip the missed dose and go back to your regular dosage schedule. Do not take a double dose (two doses at once) to make up for a forgotten 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, this medicine 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 wheeziness, 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, unusual heart beats, palpitations
- feeling dizzy, particularly when standing up
- bleeding in the stomach. Signs include passing black stools
- yellowing of the skin and whites of the eyes (jaundice)
- disease of the brain (encephalopathy)
- problems with your sight, increased pressure in the eye
- pain while passing urine or spasms of the bladder
- difficulty in breathing

Tell your doctor if you get any of these side effects:
- itching, mild skin rashes, hair loss
- muscle cramps, joint pain, back, neck or shoulder pain, pain in arms and legs
- headache, dizziness
- pins and needles in fingers and toes
- uncontrolled shaking
- restlessness, eating disorder, feeling nervous or confused
- unable to sleep or feeling sleepy
- changes in sexual drive and function, inability to achieve or maintain an erection (impotence)
- feeling depressed
- cough, blocked nose (nasal congestion)
- ringing in the ears, a feeling of spinning
- 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
- weakness, loss of appetite, fatigue
- feeling sick or being sick
- thirst or dryness of mouth
- diarrhoea or constipation
- stomach pain or wind
- heartburn, worsening of the effects of a stomach ulcer
- 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 levels, or increased potassium levels, or increased acidic level in the blood. Rise in blood urea levels
- gout

Most of the side effects of Amiloride are more likely to occur in the elderly as they are usually more sensitive to this 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 this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE AMILORIDE TABLETS

Keep this medicine out of the sight and reach of children.

Container packs: Do not store above 25°C. Keep in the original container. Keep the container tightly closed.

Blister packs: Do not store above 25°C. Store in the original package. Keep in the outer carton.

Do not use this medicine after the expiry date which is stated on the package. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Amiloride contains
The active ingredient is amiloride hydrochloride. Each tablet contains 5 mg of amiloride hydrochloride.

The other ingredients are lactose, calcium hydrogen phosphate, pregelatinised maize starch, maize starch and magnesium stearate.

What Amiloride looks like and contents of the pack
Amiloride Hydrochloride 5 mg Tablets are flat cream coloured bevelled tablets engraved MP48 on one side and scored on the other.
Amiloride Hydrochloride 5 mg Tablets are available in containers of 28, 30, 50, 56, 60, 84, 100, 250, 500 & 1000 tablets, and in blister packs of 28, 30, 50, 56, 60, 84, 100, 250, 500 & 1000 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Genesis Pharmaceuticals Limited,
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Manufacturer
DDSA Pharmaceuticals Limited,
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For any information about this medicine, please contact the Marketing Authorisation Holder.

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