

PACKAGE LEAFLET: INFORMATION FOR THE USER
Amiloride 5mg Tablets BP
(Amiloride Hydrochloride)

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Amiloride 5mg tablets are and what are they used for

Amiloride 5mg tablets belong to a group of medicines called diuretics (water tablets). Amiloride 5mg tablets can be used on their own (monotherapy) or with other drugs such as thiazide diuretics. They may be used for:

- high blood pressure
- congestive heart failure
- liver cirrhosis with swelling of the abdomen (ascites).

2. What you need to know before you take Amiloride 5mg tablets

Do not take Amiloride 5mg tablets:

- if you are allergic to amiloride hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you are giving the tablets to a **child**
- if you are taking any **potassium conserving drugs or potassium supplements**
- if you are **not producing** any urine
- if you are **pregnant** or **breastfeeding**

or if **you have:**

- **high blood levels** of **potassium** (hyperkalaemia)
- **severe kidney disease** or **kidney failure**
- **diabetic neuropathy** (diabetic nerve damage causing pain, weakness or numbness).

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 5mg tablets.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Amiloride 5mg tablets:

- if you have or have had **high levels of acid** in the body (metabolic or respiratory acidosis) caused by heart disease
- if you have **severe liver** disease

- if you have **kidney impairment**
- if you have disturbances of **blood** chemicals
- if you are **elderly**.
- if you have **diabetes**

Children

Amiloride 5mg tablets are not to be used in children

Other medicines and Amiloride 5mg tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Especially:

- **lithium** (for some mental illnesses)
- **antidiabetic drugs** such as chlorpropamide
- **ciclosporin** and **tacrolimus** (used in rheumatism, psoriasis and to prevent organ rejection)
- **medicines for high blood pressure** such as ACE inhibitors (captopril or enalapril), Angiotensin II antagonists (losartan, valsartan), beta blockers (sotolol), calcium channel blockers (amlodipine, diltiazem), adrenergic neurone blockers, alphablockers (prazosin), clonidine, diazoxide, methyldopa, moxonidine, hydralazine, minoxidil and sodium nitroprusside
- non-steroidal anti-inflammatory drugs (NSAIDs) for pain e.g. ibuprofen or naproxen
- **antidepressants** such as MAOIs, tricyclics, St Johns Wort
- **carbamazepine** (used in epilepsy)
- **aldesleukin** and **trilostane** (used in certain cancers)
- **general anaesthetic**
- **antipsychotics** such as amisulpride and pimozide, phenothiazines such as chlorpromazine or anxiolytics and hypnotics such as diazepam (used in mental illness)
- **atomoxetine** (used to treat ADHD)
- **corticosteroids** used to reduce inflammation
- **levodopa** (used in Parkinson's disease)
- **moxisylyte** (used in Raynaud's syndrome)
- **muscle relaxants** such as baclofen and tizanidine
- **nitrates** (used for certain heart conditions)
- **oestrogen** and **drospirenone** (contraception (female hormones))
- **alprostadil** (used for erectile dysfunction)
- **potassium salts**

Amiloride 5mg tablets with alcohol

Avoid alcohol when taking this medicine, your blood pressure may drop too much.

Pregnancy, breast-feeding and fertility

The use of Amiloride 5mg tablets is not recommended in pregnant women. Contact your doctor before breast feeding as you should either not breast feed or stop taking Amiloride 5mg tablets.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

If you feel dizzy while taking Amiloride 5mg Tablets do not drive or operate dangerous machinery

Amiloride 5mg tablets contain Lactose monohydrate

Amiloride 5mg tablets contain Lactose monohydrate – If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Diabetic tests

If you are to be tested for diabetes or need to have other tests related to diabetes, tell your doctor you

are taking Amiloride 5mg tablets. The tablets may need to be stopped at least three days before the test, as they can interfere with the results

3. How to take Amiloride 5mg tablets

Always take Amiloride 5mg tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Swallow the tablets.

The recommended dose is:

Monotherapy:

Two tablets a day either as a single or divided dose, to a maximum of four tablets a day and then gradually reduced to a maintenance dose.

High blood pressure:

One to two tablets a day up to four tablets a day.

Congestive heart failure:

One to two tablets a day up to four tablets a day and then gradually reduced to a maintenance dose.

Liver cirrhosis with swelling of the abdomen (ascites):

One tablet initially up to four tablets and then gradually reduced to a maintenance dose.

Elderly:

The dosage will depend on your kidney function, blood chemical levels and response to treatment. If you are elderly, it is particularly important to take this medicine exactly as prescribed.

Children:

Not recommended.

If you take more Amiloride 5mg tablets than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include dehydration and changes in the levels of certain chemicals in the blood.

If you forget to take Amiloride 5mg tablets

If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time. Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

Stop taking this medicine and go to your nearest Accident and Emergency department or contact your doctor immediately if you get any of the following signs of an allergic reaction:

- swelling of the face, lips, tongue or throat, difficulty in swallowing or breathing or a skin rash

Please tell your doctor or pharmacist if you notice any of the following side effects, they get worse or if you notice anything not listed.

- **Metabolism:** changes in levels of body chemicals (increased blood potassium or decreased blood sodium).
- **Nervous system:** depression, difficulty sleeping or sleepiness, confusion, nervousness, dizziness, pins and needles, feeling of spinning (vertigo), tremors and brain disease (characterised by poor concentration, confusion and delirium).
- **Heart:** chest pain (angina), irregular (arrhythmia) or pounding (palpitation) heart beats, dizziness on standing due to low blood pressure, heart block.
- **Breathing:** cough, difficulty breathing.
- **Stomach and intestines:** stomach pain or bleeding, indigestion, wind, loss of appetite, thirst, constipation, diarrhoea, feeling or being sick, dry mouth.
- **Liver and pancreas:** jaundice (yellow skin or eyes).
- **Skin:** skin rash, itching, hair loss.
- **Muscles and joints:** joint pain, muscle cramps, gout.
- **Urinary and genital:** pain on passing water, frequent or copious water production, bladder spasms, decreased desire for sex and inability to maintain an erection.
- **Senses:** stuffy nose, ringing in the ears, increased pressure in the eyes, visual disturbances.
- **Other:** back, chest, neck and shoulder pain, pain in the hands and feet, tiredness, weakness, headache.

Reporting of side effects If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this 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 5mg tablets

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 in order to protect from light.

Keep out of the reach and sight of children.

Do not use your tablets after the expiry date stated on the carton or label. The expiry date refers to the last day of that month.

Medicines should not be disposed of via waste water 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 5mg Tablet contains

The **active** substance is Amiloride hydrochloride.

The **other** ingredients are Lactose monohydrate, Dibasic calcium phosphate dihydrate, Pregelatinised starch, Maize starch, Sodium starch glycolate and Magnesium stearate (*see section 2 for Important information about some of the ingredients of Amiloride 5mg tablets*).

What Amiloride 5mg tablets looks like and contents of the pack

Amiloride 5mg tablets are off white to creamy white, round, flat, uncoated, debossed with C and G on either side of the breakline and plain on the another side.

They are available in container packs of 100 and 500 tablets. They are also available in the blister packs of 28 and 84 tablets (Not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in 10/2016.