

Package leaflet: Information for the user

Bumetanide/Amiloride 1mg/5mg Tablets

bumetanide and 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 or pharmacist.
- This medicine has been prescribed 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet

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1. What Bumetanide/Amiloride Tablets are and what they are used for

Bumetanide/Amiloride Tablets contain two different medicines. One medicine is called bumetanide and the other medicine is called amiloride hydrochloride. These both belong to a group of medicines called diuretics (water tablets). Bumetanide/Amiloride works by removing any excess water from your body. It will make you go to the toilet more.

Bumetanide/Amiloride is used to treat oedema. Oedema means that there is too much water in your body. Oedema can cause symptoms such as swollen ankles or trouble breathing.

2. What you need to know before you take Bumetanide/Amiloride Tablets

Do not take Bumetanide/Amiloride Tablets:

- if you are allergic to bumetanide or amiloride hydrochloride, or any of the other ingredients of this medicine (listed in section 6).
- if you know that you have any sugar intolerance. You may have inherited this condition from someone else in your family.
- if you cannot pass water (urine) at all.
- if you have severe kidney problems or severe liver problems such as cirrhosis.
- if you know you have a condition called Addison's disease.
- if you have been told that you have high levels of potassium in your blood.
- if you have been told that you have low levels of certain salts in your blood.
- if you are taking potassium supplements or any medicines that may change the amount of potassium in your body. Ask your doctor if you are not sure.

Warnings and precautions

Talk to your doctor or pharmacist before taking Bumetanide/Amiloride Tablets:

- if you have diabetes
- if you have gout
- if you have prostate problems or have difficulty passing urine
- if you are vomiting or have diarrhoea
- if you have low blood pressure
- if you have a condition called porphyria

- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Bumetanide/Amiloride Tablets or other sulphonamides, e.g., loop diuretics.
- if you have liver disease
- if you are allergic to medicines called sulfonamides or thiazides
- if you are an athlete who undergoes doping testing.

Serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported in association with Bumetanide/Amiloride Tablets treatment. Stop using Bumetanide/Amiloride Tablets and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

When you are taking Bumetanide/Amiloride Tablets your doctor may take regular blood tests. This is very important in the elderly, in diabetics or in seriously ill patients.

If you are going to have a "glucose tolerance test" tell the doctor or nurse you are taking Bumetanide/Amiloride Tablets as this may affect the results.

Blood tests

Tell your doctor if you are having blood tests as your medicine may cause changes in the level of some substances in your blood (including salts, sugar, waste products and body fats such as cholesterol and triglycerides).

Other medicines and Bumetanide/Amiloride Tablets

Tell your doctor or pharmacist if you are taking, or have recently taken, or might take any other medicines. This includes any medicines which you have bought without a prescription.

Do not take Bumetanide/Amiloride if you are taking potassium supplements or any medicines that may change the amount of potassium in your body.

You must tell your doctor or pharmacist if you are taking any of the following medicines:

- medicines for heart conditions, such as digoxin, ACE inhibitors, angiotensin II receptor antagonists. Your doctor may need to change your dose
- medicines for high blood pressure. This includes alpha-blockers such as prazosin or indoramin which can also be used for prostate problems in men
- non-steroidal anti-inflammatory drugs, such as ibuprofen, for arthritis or aches or pains
- lithium, used for mental illnesses. To help stop side effects your doctor may need to change the dose of your lithium and check the amount of lithium in your blood
- any medicines that make you feel dizzy on standing up e.g. tricyclic antidepressants such as amitriptyline
- medicines for diabetes. Your doctor may need to change your dose
- any medicines that may affect your kidneys
- cephalosporin antibiotics
- aminoglycoside antibiotics (e.g. gentamicin) or other medicines which may affect your hearing
- tetracycline antibiotics (e.g. oxytetracycline)
- probenecid, a medicine used in special cases, to protect the kidneys
- ciclosporin, a medicine used to suppress the immune system
- trilostane, a medicine used to stop excessive production of steroids, or in women with breast cancer.

Pregnancy and breast-feeding

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

Driving and using machines

This medicine may cause dizziness, drowsiness, tiredness or feeling faint as side effects. You must not drive or use machines if you get any of these side effects.

Bumetanide/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 Bumetanide/Amloride Tablets

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

Dosages

Your doctor will tell you how many tablets to take.

You are likely to need the toilet more often after you have taken your tablets. Remember that this may be inconvenient if you are going on a long journey or want to go to sleep.

Remember to always take this medicine with at least half a glass of water. Take your tablets at the same time each day.

This makes it easier to remember them.

Adults and the elderly

The recommended dose is one or two tablets each day. Your doctor may change your dose depending on your test results.

If you forget how many tablets to take, look at the label on your pack.

If you are still not sure, ask your doctor or pharmacist.

Use in children and adolescents

This medicine is not suitable for children or adolescents (under the age of 18 years).

Method of administration

The score line is not intended for breaking the tablet.

If you take more Bumetanide/Amloride Tablets than you should

Tell your doctor straight away. You may need to stop taking this medicine.

If you forget to take Bumetanide/Amloride Tablets

If you forget to take your medicine, and you are less than 12 hours late, you can still take it. If you are more than 12 hours late taking your medicine then leave out this dose. Take the next dose at the usual time.

Do not take a double dose to make up for a forgotten dose.

If you have any further questions about taking this medicine, please ask your doctor or pharmacist.

4. Possible side effects

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

STOP using Bumetanide/Amloride Tablets and seek medical attention immediately if you notice any of the following symptoms:

- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [Stevens-Johnson syndrome, toxic epidermal necrolysis].

You must get medical help straight away if you have any of the following symptoms. You may be having a severe allergic reaction:

- difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised lumps

Seek immediate medical attention if you have any of the following symptoms:

- you feel shaky, faint or your heart starts to beat fast or irregularly. This may be due to a shock-like reaction

- fever, rash, feeling sick, aches and pains, loin pain, passing more or less urine than usual, passing red urine or passing urine at night, difficulty or inability to pass urine. This may be due to changes in your kidneys
- you have liver problems and you feel confused, forgetful or faint, or if your skin or eyes become yellow, or if you have pale faeces, dark urine or itchy skin
- unusual or increased bleeding or bruising
- fever, sore throat, mouth ulcers, repeated infections that keep coming back
- feeling tired, breathless, looking pale.

Tell your doctor if you get any of the following side effects:

Digestive problems:

- feeling or being sick
- indigestion, heartburn
- stomach pain or cramps, wind
- diarrhoea, constipation.

Skin problems:

- rash, including dermatitis
- itching skin
- itchy raised skin (hives)
- reactions to the sun. Your skin may become red, painful and swollen - do not sunbathe, use a sunbed, or expose your skin to UV light.

Other problems:

- noticing your heart beats which may be slower or faster than usual
- chest pain (angina)
- swollen or painful breasts (sometimes in men)
- erectile problems, decreased sexual drive
- muscle cramps or pain
- pain in your bones and muscles. This may happen if you are taking high doses and have severe kidney problems
- pain and swelling in one or more joints (gout)
- tingling or numbness sensation
- headache
- confusion
- ringing or buzzing in the ears (tinnitus), deafness
- you feel unusually thirsty with dry skin, dark urine, dry mouth, headache. This may be due to dehydration
- you feel dizzy or have 'head spins'
- light-headedness or dizziness when standing up from a sitting or lying position
- a collection of symptoms including thirst, frequent urination, tiredness, and increased susceptibility to infection, such as thrush. This may be due to too much glucose in the body. Your doctor can test for this
- you feel drowsy or tired.

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 or search for MHRA Yellow Card in the Google Play or Apple Store.

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

5. How to store Bumetanide/Amloride Tablets

Keep out of the sight and reach of children.

Do not use the tablets after the expiry which is stated on the carton after EXP. The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information

What Bumetanide/Amiloride Tablets contains

The active substances are bumetanide and amiloride hydrochloride. Each tablet contains 1 mg bumetanide and 5 mg amiloride hydrochloride.

The other ingredients are lactose, magnesium stearate, maize starch and microcrystalline cellulose (see end of section 2 for further information on lactose).

What Bumetanide/Amiloride Tablets look like and contents of the pack

Bumetanide/Amiloride Tablets are cream oval tablets, with a break line on one side and marked '149' on the reverse.

They are available in blister packs of 14, 28, 56 tablets, and bottles of 50 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Chemidex Pharma Ltd, trading as Essential Generics, 8a Crabtree Road, Egham, Surrey TW20 8RN.

Manufacturer

Lelypharma B.V., Zuiveringweg 42, 8243 PZ Lelystad, the Netherlands.

Dales Pharmaceuticals Ltd, Snaygill Industrial Estate, Keighley Road, Skipton BD23 2RW.

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