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Package leaflet: Information for the patient

Bumetanide 1 mg and 5 mg tablets

bumetanide

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:

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

1. What Bumetanide is and what it is used for

Bumetanide belongs to a group of medicines called diuretics (or 'water' tablets). Diuretics act on the kidneys to increase the flow of urine. This gets rid of excess water from your body and reduces the effect of water build up.

Bumetanide can be used to help get rid of excess water in your body, which may be caused by medical problems such as heart failure, liver or kidney disease.

2. What you need to know before you take Bumetanide

Do not take Bumetanide if you:
- are allergic to bumetanide, sulfonamide medicines (which may include some medicines used to treat infections e.g. co-trimoxazole or other diuretic medicines such as hydrochlorothiazide) or any of the other ingredients of this medicine (listed in section 6).
- are taking lithium to treat manic depression
- are in a coma caused by liver problems
- are passing less urine than usual, or not passing urine at all
- know that you have severe (very low or very high) changes in your blood "salt" levels (sodium, potassium, chloride or bicarbonate)
- know that you have a high level of urea in the blood

Warnings and precautions

Talk to your doctor or pharmacist before taking Bumetanide if you:
- are on a low salt diet
- have liver or kidney problems
- suffer from gout
- have diabetes, or are at risk of developing diabetes (your doctor may have told you, for example, that you have higher than normal levels of sugar in the blood after eating)
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Bumetanide or other sulphonamides, e.g., loop diuretics.

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

During treatment

Whilst taking this medicine, you may need to have blood tests, as advised by your doctor, to check levels of certain salts in the blood.

Other medicines and Bumetanide

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

Do not take Bumetanide with:
- Lithium, normally used to treat manic depression (see section 'Do not take' above)

If you are taking any of the following medicines, tell your doctor or pharmacist before taking Bumetanide:
- some antibiotics used to treat infections such as cephaloridine or gentamicin
- amphotericin, normally used to treat fungal infections
- treatment for a heart condition such as digoxin
- treatment for high blood pressure such as sotalol, or medicines known as ACE inhibitors such as captopril
- an anti-inflammatory medicine, normally used for arthritis or other bone and muscle problems such as indometacin, ibuprofen, diclofenac

If you are taking any of the above medicines your doctor may need to adjust your dose of Bumetanide or the dose of the other medicine you are taking.

Pregnancy and breast-feeding

Bumetanide should not be given to pregnant or breast-feeding mothers unless the benefits to the mother outweigh the risks to the baby. 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.

Driving and using machines

This medicine should not normally have any effect on your ability to drive or operate machines. However, this medicine may cause dizziness, tiredness, weakness or cause confusion as side effects. You must not drive or use machines if you get any of these side effects.

Bumetanide contains lactose

If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicine.

3. How to take Bumetanide

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

At the start of treatment your doctor may monitor your condition closely.

Adults

The usual recommended starting dose is 1 mg a day. This dose can be taken in the morning or early evening. In some cases an additional 1 mg may be given 6 to 8 hours after your first dose.

If your condition is not controlled by a lower dose, or you are being treated for a severe build-up of fluid (oedema), you may need to take up to 5 mg a day. If there is still no response, your doctor may increase your dose until your fluid build up is controlled. If you are taking more than one tablet a day it may be recommended that you take one dose in the morning and one dose in the early evening.

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Elderly
Your doctor may adjust your dose to make sure the dose is right for you.

Use in children
Bumetanide is not recommended for use in children under 12 years old.

If you take more Bumetanide than you should
Contact your doctor or nearest hospital emergency department **immediately**. Take the container and any remaining tablets with you.

If you forget to take Bumetanide
Take the next dose as soon as you remember unless it is almost time for your next dose. **Do not** take a double dose to make up for a forgotten dose. If you keep forgetting to take your medicine, tell your doctor.

If you stop taking Bumetanide
Do not suddenly stop taking your medicine unless your doctor told you. If you stop taking this medicine, the fluid build-up in the body may return. Therefore, before you stop taking bumetanide, talk to your doctor or pharmacist for advice.

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.
Stop using Bumetanide and seek medical attention immediately if you notice any of the following symptoms:
- difficulty breathing (which may feel like an asthma attack), raised, red very itchy skin rash (hives) or an itchy, runny nose. These may be signs of an allergic reaction.
- in people with liver problems, due to a build-up of potentially harmful substances in the body, confusion, drowsiness and difficulty performing normal tasks such as writing may occur. In some instances, this may lead to a loss of consciousness (coma).
- passing little or no urine.
- 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].

Other side effects are:
Common (may affect up to 1 in 10 people):
- dehydration (reduced fluid in the body), which may make you feel thirsty
- headache
- low blood pressure, which can make you feel dizzy especially when standing up
- feeling sick
- in people with liver problems, itching of the skin
- feeling unusually tired

Uncommon (may affect up to 1 in 100 people):
- severe loss of fluid and salts from the body – you may feel very weak or confused
- vertigo (a spinning sensation)
- earache
- diarrhoea
- painful breasts or chest discomfort

Rare (may affect up to up to 1 in 1,000 people):
- hearing disturbances
- reduction in the activity of the bone marrow (where blood cells are produced), which may be seen in blood tests

Not known (cannot be estimated from the available data):
- unusual bleeding or bruising of the skin
- stomach ache or cramps
- being sick
- indigestion or heartburn
- skin rash
- muscle cramps. In people taking very high doses of this medicine, these may be severe and long-lasting (up to 12 hours) and you may also notice muscle and bone pain across the whole body.
- joint pain
- swelling or growth of the breasts
- raised blood levels of uric acid, urea and creatinine or changes in liver enzymes (which show how the liver is working) in the blood, which may be seen in blood tests
- raised levels of sugar in the blood

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

5. How to store Bumetanide

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

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

This medicine does not require any special storage conditions.

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 Bumetanide contains
The active substance is bumetanide. Each tablet contains either 1 mg or 5 mg of bumetanide.
The other ingredients are lactose monohydrate, maize starch, pregelatinised maize starch, microcrystalline cellulose and magnesium stearate.

What Bumetanide looks like and contents of the pack
Your medicine is available in two strengths 1 mg and 5 mg, both are a white tablet. The 1 mg tablets are marked 'BU/1' on one side and 'G' on the other and the 5 mg tablets are marked 'BU/5' on one side and 'G' on the other.

Bumetanide is available in blisters and containers of 5, 7, 10, 14, 15, 20, 21, 25, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 168 and 180 tablets. Not all pack sizes and pack types may be marketed.

Marketing Authorisation Holder
Viatris,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom.

Manufacturer
Mylan Hungary Kft, Mylan utca 1, Komárom, 2900, Hungary

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