

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

1. What Bumetanide Oral Solution is and what it is used for

Bumetanide Oral Solution contains bumetanide which is a diuretic (water medicine).

It is used where there is too much water in your body. Bumetanide helps your kidneys produce more urine over a short period of time which means that your body can get rid of more water quickly.

It is effective for people who have swollen feet and ankles due to fluid which has built up as a result of heart, liver or kidney disease.

There are other reasons why you may need a diuretic.

Speak to your doctor if you are not sure why this medicine has been prescribed for you.

2. What you need to know before you take Bumetanide Oral Solution

Do not take Bumetanide Oral Solution:

- if you are allergic to bumetanide or any of the other ingredients of this medicine (listed in section 6)
- if you cannot pass water (urine)
- if you are dehydrated (thirsty with dry skin, dark urine, dry mouth, headache)
- if you have been told by your doctor that you have low levels of salts in your body.

If any of the above apply to you, speak to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor before taking Bumetanide Oral Solution:

- if you are on a low salt diet
- if you have diabetes
- if you have long-term kidney disease
- if you have liver disease
- if you have low blood pressure
- if you have a condition called porphyria
- if you have high levels of uric acid in your blood. Your doctor may test your blood for this
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Bumetanide Oral Solution or other sulphonamides, e.g., loop diuretics.
- if you are an athlete who undergoes urine doping testing.

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

Children

Do not give this medicine to children under 12 years of age.

Other medicines and Bumetanide Oral Solution

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

- 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
- aminoglycoside antibiotics (e.g. gentamicin) or other medicines which may affect your hearing
- cardiac glycosides (e.g. digoxin), used to treat heart conditions
- medicines for high blood pressure
- non-steroidal anti-inflammatory medicines (e.g. indometacin)
- medicines which may affect your kidneys.

Pregnancy, breast-feeding and fertility

DO NOT take Bumetanide if you are pregnant or while breast-feeding unless advised to by your doctor.

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 this medicine.

Driving and using machines

Bumetanide Oral Solution may cause dizziness or tiredness. If this occurs do not drive, use machinery, or perform any tasks that may require you to be alert.

Bumetanide Oral Solution contains:

- **Sorbitol**
This medicine contains 1375 mg sorbitol in each spoonful (5 ml) which is equivalent to 275 mg/ml. Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

- **Methyl parahydroxybenzoate and propyl parahydroxybenzoate**
These may cause allergic reactions (possibly delayed).
- This medicine contains less than 1 mmol sodium (23 mg) per spoonful (5 ml), that is to say essentially ‘sodium-free’.

3. How to take Bumetanide Oral Solution

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

- Take your medicine at the same time each day, usually in the morning or early evening; this makes it easier to remember.
- If you are taking more than 5 ml a day, you may need to take two doses rather than taking all your medicine in one go. Remember that this may be inconvenient if you are going on a long journey or want to go to sleep.
- You are more likely to need the toilet for about 3 hours after you have taken your medicine.
- You may like to have a drink of water after taking the medicine.

The recommended dose is:

Adults, adolescents and children over 12 years: the usual starting dose is 5 ml once a day.

Your doctor may change your dose after you have been taking this medicine for a while.

Elderly: you may be given a lower starting dose as you may be more sensitive to this medicine.

Use in children

This medicine is NOT suitable for children under 12 years.

Patients with severe kidney problems: if you have kidney failure and are taking a high dose of Bumetanide Oral Solution, you will be given this medicine in hospital under special care.

Blood tests may be carried out to check how well this medicine is working, particularly in patients taking a low salt diet.

Diabetics may have their blood and urine checked.

If you take more Bumetanide Oral Solution than you should

1. Tell your doctor, pharmacist or nearest hospital casualty department immediately.
2. Take the bottle and any remaining solution with you so that people can see what you have taken.
3. Do this even if you feel well.

If you forget to take Bumetanide Oral Solution

If you forget to take a dose, take it as soon as you remember if it is less than 12 hours late.

If you are more than 12 hours late taking your medicine, skip the forgotten dose and continue as usual.

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

If you stop taking Bumetanide Oral Solution

Do not stop taking this medicine, or lower the dose yourself, without first checking with your doctor.

Keep taking the solution until your doctor tells you to stop. Do not let yourself run out of medicine especially over the weekend or on holidays.

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. Do not be alarmed by this list of possible side effects. You may not experience any of them.

STOP taking the solution and **seek medical help immediately** if you have any of the following **allergic reactions**:

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

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

- feeling 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
- unusual or increased bleeding or bruising
- fever, sore throat, mouth ulcers, repeated infections or infections that will not go away
- feeling tired, breathless and looking pale
- yellowing of your skin or eyes, pale faeces and dark urine, itchy skin. This may be due to blockage in the liver.

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

- 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)
- feeling thirsty with dry skin, dark urine, dry mouth, headache. This may be due to dehydration
- light-headedness or dizziness when standing up from a sitting or lying position

- reactions to the sun. Your skin may become red, painful and swollen - do not sunbathe, use a sun bed, or expose your skin to UV light
- a collection of symptoms including thirst, frequent urination, tiredness, and increased susceptibility to infections, such as thrush. This may be due to too much glucose in the body. Your doctor can test for this.

The following side effects usually settle without changing the dose:

- headache
- stomach ache, feeling sick or being sick, diarrhoea
- muscle cramps or pain
- itchy raised skin (hives)
- itching skin, skin rashes including dermatitis
- swollen or painful breasts (sometimes in men)
- ringing or buzzing in the ears (tinnitus), deafness
- dizziness
- feeling tired.

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).

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 Oral Solution

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 bottle label and on the carton after EXP. The expiry date refers to the last day of that month. Store below 25°C. 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 Oral Solution contains

- The active substance is bumetanide. 5 ml oral solution contains 1 mg bumetanide.
- The other ingredients are sorbitol (E 420), methyl parahydroxybenzoate (E 218), propyl parahydroxybenzoate (E 216), xanthan gum, sodium citrate, patent Blue V, quinoline yellow, peppermint flavour and purified water. (See end of Section 2 for further information on sorbitol, methyl parahydroxybenzoate and propyl parahydroxybenzoate).

What Bumetanide Oral Solution looks like and contents of the pack

Bumetanide Oral Solution is a clear, green liquid with the flavour of peppermint. It is available in amber glass bottles of 5 ml, 10 ml, 25 ml and 150 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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

Manufacturer

Delpharm Bladel BV, Industrieweg 1, 5531 AD Bladel, The Netherlands.

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