

Bendroflumethiazide 2.5mg and 5mg tablets

Read all of this leaflet carefully before you start taking this medicine.

- 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.

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1 What Bendroflumethiazide tablets are and what they are used for

Bendroflumethiazide tablets belong to a group of medicines called thiazide diuretics (water tablets). They may be used to:

- reduce fluid retention (oedema) particularly in the heart, kidneys, liver or that caused by medication, by increasing the flow of urine.
- reduce high blood pressure alone or with other medication.

2 Before you take

Do not take Bendroflumethiazide tablets and **tell your doctor if you have:**

- an **allergy** (hypersensitivity) to thiazides or any of the other ingredients in Bendroflumethiazide tablets (see section 6).
- severely impaired **kidney or liver** function.
- **high blood levels of calcium** (hypercalcaemia).
- **low blood levels of sodium** (hyponatraemia).
- **low blood levels of potassium** which has not responded to treatment (refractory hypokalaemia).
- or have had **gout** (high levels of uric acid in the blood), causing crystals to deposit in joints of hands or feet causing pain (hyperuricaemia).
- **Addison's disease** (syndrome due to low level of corticosteroid hormones secretion, symptoms include weakness, loss of energy, low blood pressure and dark pigmentation of the skin).

Check with your doctor or pharmacist before taking Bendroflumethiazide tablets if you have:

- mild or moderate impaired **kidney or liver** function.
- **liver** disease caused by alcohol (alcoholic cirrhosis).
- or may have **diabetes**. If you are taking insulin, your doctor may need to adjust your insulin dosage.
- **systemic lupus erythematosus (SLE)** (an inflammatory disease of connective tissue causing large areas of red scaly patches on the face, hair loss, weight loss, painful joints and fever).
- an inherited disorder of the red blood pigment haemoglobin causing skin blisters, abdominal pain and brain or nervous system disorders (**porphyria**).

Taking other medicines

Please **tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- allopurinol (used in gout)
- colestyramine or colestipol (used to lower cholesterol)
- disopyramide, amiodarone, flecainide, quinidine, lidocaine or mexiletine (used to control an irregular heart beat)
- tricyclic antidepressants, reboxetine or monoamine-oxidase inhibitors (MAOIs) (used for depression)
- sulfonylureas (used in diabetes to control blood sugar levels)
- carbamazepine (used in epilepsy)
- amphotericin (used to treat fungal infections)
- prazosin (used in high blood pressure, heart failure, Raynaud's syndrome and an enlarged prostate)
- ACE inhibitors (e.g. enalapril) or angiotensin-II antagonists (e.g. losartan) used to lower blood pressure
- pimozone or thioridazine (antipsychotics)
- calcium salts
- calcium channel blockers e.g. amlodipine or diltiazem
- moxislyte (used in Raynaud's syndrome)
- corticosteroids e.g. prednisolone
- cisplatin (used to treat cancer)
- digoxin (used to treat some heart problems)
- aminoglutethamide (used in some cancers and Cushing's syndrome)
- toremifene (used in some cancers)
- lithium (used for mental health problems)
- muscle relaxants such as baclofen, tizanidine, tubocurarine, gallamine, alcuronium or pancuronium
- NSAIDs (non-steroidal anti-inflammatory drugs) such as indometacin, ketorolac, ibuprofen, piroxicam or naproxen
- oestrogens and combined oral contraceptives
- sympathomimetics (used as decongestant, asthma or heart medicine)
- theophylline (used in breathing problems such as asthma)
- carbenoxolone (an ulcer healing drug)
- vitamin D.

Pregnancy and breast-feeding

Bendroflumethiazide tablets should not be used in pregnant or breast-feeding women. Speak to your doctor or pharmacist before taking any medicine.

Driving and using machines

Bendroflumethiazide tablets can cause dizziness, make sure you are not affected before driving or operating machinery.

Sugar intolerance

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains a type of sugar called lactose.

Tests

During treatment with Bendroflumethiazide tablets, your doctor may want to monitor your kidney function. If you are elderly or on long term treatment with Bendroflumethiazide tablets, your doctor may want to monitor the level of chemicals in your body, by carrying out tests.

3 How to take

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

Swallow the tablets **with water in the morning** (to avoid frequent urination at night).

Doses:

Adults and children 12 years and over

Oedema: initially 5-10mg once a day or once every other day. The maintenance dose is 2.5-10mg two or three times a week.

High blood pressure: 2.5-5mg once a day.

Children under 12 years

A more appropriate formulation may be used.

Initially 400micrograms per kilogram of body weight, a day. The maintenance dose is 50-100micrograms per kilogram of body weight, a day.

Elderly

Your doctor may prescribe you a lower dose especially if you have impaired kidney function.

If you take more 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 feeling or being sick, diarrhoea, dehydration, dizziness, weakness, muscle cramps, increase in the frequency and amount of urination, thirst, decreased volume within blood vessels, low blood pressure, circulation problems (peripheral circulatory failure), low blood levels of potassium (hypokalaemia) and sodium (hyponatraemia), low blood sugar levels (hypoglycaemia) and central nervous system depression (drowsiness, tiredness and coma).

If you forget to take the 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.

4 Possible side effects

Like all medicines, Bendroflumethiazide tablets can cause side effects, although not everybody gets them.

Contact your doctor at once if you experience the following:

- **Allergic reaction** (hypersensitivity): rashes including skin that is red, flaky and peeling (exfoliative dermatitis), sensitivity to sunlight or artificial light (e.g. sun beds), a viral infection of the lungs (pneumonitis), fluid in the lungs (pulmonary oedema).
- **Blood:** altered numbers and types of blood cells. If you notice increased bruising, nosebleeds, sore throats, infections, excessive tiredness, breathlessness on exertion or abnormal paleness of the skin, you should tell your doctor who may want you to have a blood test.

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

- **Metabolism:** decreased carbohydrate tolerance, worsening of existing diabetes, increased blood levels of uric acid, worsening of gout, changes in blood lipid (fat) levels.
- **Chemicals within the body:** low blood potassium levels (hypokalaemia) (which may cause an increase in the frequency and amount of urination, a feeling of general discomfort and illness, muscle weakness or cramp, dizziness, feeling or being sick and loss of appetite), low blood magnesium and sodium levels, high blood levels of calcium (hypercalcaemia), low blood levels of chloride ions with increased alkalinity in the body (hypochloraemic alkalosis).
- **Stomach and intestines:** feeling or being sick, diarrhoea, constipation, stomach irritation.
- **Other:** inflammation of the pancreas, blocked bile flow within the liver, inability to maintain an erection, dizziness on standing due to low blood pressure (postural hypotension), dizziness.

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

5 How to store

Keep out of the reach and sight of children.

Store below 25°C in a dry place.

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What Bendroflumethiazide tablets contain

- The active substance (the ingredient that makes the tablets work) is bendroflumethiazide PhEur. Each tablet contains either 2.5mg or 5mg of the active substance.
- The other ingredients are lactose, magnesium stearate, maize starch, pregelatinised maize starch, stearic acid, water.

What Bendroflumethiazide tablets look like and contents of the pack

2.5mg tablets are white, circular, biconvex, uncoated tablets.

5mg tablets are white, circular, flat bevelled-edge, uncoated tablets.

Pack size is 28.

Marketing Authorisation Holder and Manufacturer

Actavis, Barnstaple, EX32 8NS, UK.

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