Bendroflumethiazide 2.5mg & 5mg Tablets PIL - UK

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 legs, feet and abdomen,
- reduce high blood pressure alone or with other medicines,
- 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.

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 4).
- 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 corticosteroids 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).
- sulphonylureas (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.
- pimozide or thioridazine (antipsychotics).
- calcium salts.
- calcium channel blockers e.g. amlodipine or diltiazem.
- moxisylyte (used in Raynaud’s syndrome).
- corticosteroids e.g. prednisolone.
- cisplatin (used to treat cancer).
- digoxin (used to treat some heart problems).
- aminoglutethimide (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 Raynaud’s syndrome and an enlarged prostate).
- lidocaine or mexiletine (used to control an irregular heart beat).
- theophylline (used in breathing problems such as asthma).
- ciclosporin (used in organ transplants).
- 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.

For the full list of medicines and their doses, see section 4.

Possible side effects
Common side effects that may affect more than 1 in 10 people:
- dry mouth.
- loss of appetite.
- nausea.
- increased frequency of passing urine.
- feeling extremely tired or weak.
- loss of muscle strength.
- difficulty in passing urine.
- feeling dizzy.

Rare side effects that may affect less than 1 in 10 people:
- headache.
- diarrhoea.
- constipation.
- flatulence.
- painful or frequent urination.
- skin rash or itching.
- eye problems.
- unusual tiredness or weakness.
- shortness of breath.
- swelling of hands and feet.
- breathing difficulties.
- feeling faint.
- feeling light-headed.
- confusion.
- feeling irritable.
- dizziness.
- weakness.
- loss of balance.
- loss of coordination.
- change in colour of urine.
- more frequent or painful menstruation.
- acne.
- sweating.
- enlarged or tender breast.
- reduced sex drive.

If you have any further questions, ask your doctor or pharmacist. If you get any side effects, talk to your doctor or pharmacist. You may need to stop taking. It may harm them even if their symptoms are the same as yours.

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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 (hyponatremia), 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): rash including skin that is red, itchy 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 (hypocalcaemia), low blood levels of chloride ions with increased alkalinity in the body (hypochloremic 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.

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
Keep out of the sight and reach 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.

This leaflet was last revised in March 2017

Bendroflumethiazide Tablets
All strengths x 28s (UK)

Item no: BBBA0566
Originator: S.Anson
Revision Date: 27/02/17
Supplier: Actavis UK
Min Body Text Size: 7pts
Dimensions: 148 x 210
Pharmocode: 4874
Technical Approval: R.Wrey

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