Bendroflumethiazide 2.5mg and 5mg tablets

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 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 What you need to know before you take Bendroflumethiazide tablets

Do not take Bendroflumethiazide tablets if you:
- are **allergic** to bendroflumethiazide, to thiazides or to any of the other ingredients of this medicine (listed in section 6)
- have severely impaired **kidney** or **liver** function
- have **high blood levels** of **calcium** (hypercalcaemia)
- have **low blood levels** of **sodium** (hyponatraemia)
- have **low blood levels** of **potassium** which has not responded to treatment (refractory hypokalaemia)
- have **gout** (high levels of uric acid in the blood), causing crystals to deposit in joints of hands or feet causing pain (hyperuricaemia)
- have **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).

Warnings and precautions
Talk to your doctor or pharmacist before taking Bendroflumethiazide tablets if you:
- have a **heart problem** such as **prolonged QT intervals**, **severe heart disease** or **arrhythmias**
- have **heart failure with water retention**, particularly if you are on a **salt restricted diet**
- have **liver** or **kidney problems**
- have **magnesium deficiency**
- are **elderly**
- have **cirrhosis of the liver**
- have **hyperparathyroidism**
- experience a **decrease in vision or eye pain.** These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to a week of taking Bendroflumethiazide tablets. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this
- have experienced **sensitivity to sunlight** or **artificial light** (e.g. sun beds) when taking thiazides/thiazide-related diuretics
- have **systemic lupus erythematosus (SLE)**
- have **pancreatitis**
- have had **gout**
- have **diabetes.** If you are taking insulin, your doctor may need to adjust your insulin dosage
- have **high blood cholesterol**.

Other medicines and Bendroflumethiazide tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Especially:
- aldeskin, toremifene, cisplatin (used in cancer treatment)
- anaesthetics (tell your doctor, dentist or nurse if you are having any planned surgery)
- trimethoprim (to treat infections)
- antidepressants, e.g. tricyclics, monoamine oxidase inhibitors (MAOIs)
- chlorpropamide, insulin (used in diabetes)
- amphotericin (to treat fungal infections)
- angiotensin-converting enzyme (ACE) inhibitors, angiotensin-II antagonists, calcium channel blockers, beta-blockers, alpha-blockers (e.g. prazosin), hydralazine, diazoxide or methyldopa (for high blood pressure)
- barbiturates (used in anxiety or insomnia)
- vitamin D
- moxisylyte (for circulatory disorders)
- corticosteroids, e.g. cortisone, hydrocortisone (for inflammatory conditions), adrenocorticotropic hormone (ACTH) (used to stimulate cortisol production)
- acetazolamide (for glaucoma), loop diuretics (for high blood pressure and water retention)
- levodopa (for Parkinson's disease)
- aminoglutethimide (for epilepsy, Cushing's syndrome and cancer)
- nitrates (for angina)
- opioids (for pain relief)
- alprostadil (for erectile dysfunction)
- theophylline, beta-2 sympathomimetics (for asthma)
- carbenoxolone (to treat ulcers and inflammation)
- colestipol and colestyramine (for high blood cholesterol)
- non-steroidal anti-inflammatory drugs (NSAIDs), e.g. indomethacin, ketorolac, ibuprofen, piroxicam, naproxen
- oestrogens, combined oral contraceptives
- disopyramide, amiodarone, flecainide, quinidine, mexiletine, sotalol (for heart arrhythmias)
- allopurinol (for gout)
- astemizole, terfenadine (for allergies)
- halofantrine (antimalarial)
- pimozide, sertindole, thioridazine, phenothiazines (antipsychotics)
- ciclosporin (immunosuppressant)
- digoxin (for heart conditions)
- lithium (for mental health problems)
- tubocurarine, gallamine, alcuronium, pancuronium, tizanidine (muscle relaxants)
- carbamazepine (used in epilepsy)
- calcium salts.

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If you are having parathyroid function tests, speak to your doctor as Bendroflumethiazide tablets may affect the results.

Bendroflumethiazide tablets and alcohol
Consuming alcohol whilst taking this medicine may make you feel dizzy or faint when you stand.

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.

Bendroflumethiazide 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 medicine.

3 How to take Bendroflumethiazide tablets
Always take Bendroflumethiazide tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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

The recommended dose is:

Adults and children 12 years and over
Oedema: initially 5-10mg once a day or once every other day. The maintenance dose is 5-10mg one to three times a week.
High blood pressure: 2.5mg 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 Bendroflumethiazide tablets 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 emergency department or tell your doctor immediately. Symptoms of an overdose include lack of appetite, feeling or being sick, diarrhoea, dehydration, low blood pressure, dizziness, weakness, muscle cramps, fits, increase in the frequency and amount of urination, thirst, pins and needles, muscle spasms, changes in the levels of salts and electrolytes in your blood, heart rhythm abnormalities and central nervous system depression (drowsiness, tiredness and coma).

If you forget to take Bendroflumethiazide 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.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

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

Contact your doctor or emergency department at once if you experience the following:
Rare (may affect up to 1 in 1,000 people):
- 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.
- pancreatitis (pain or tenderness in the upper abdomen, feeling or being sick, fever)

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Not Known (frequency cannot be estimated from the available data):
- allergic reactions (rash, itching, swelling of the mouth or throat), a viral infection of the lungs (pneumonitis), fluid in the lungs (pulmonary oedema) which may cause breathing difficulties, rashes including; skin that is red, flaky and peeling (exfoliative dermatitis), raised, red and itchy rashes, ring-like rashes (erythema multiforme), blistering skin (pseudoporphyria)
- systemic lupus erythematosus (causing tiredness and joint pain)
- decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye [choroidal effusion] or acute angle-closure glaucoma)
- blocked bile flow within the liver (yellowing of the skin or whites of the eyes, dark urine and pale stools)
- inflammation in the kidney (increased or decreased need to urinate, blood in the urine, fever or pain)

Tell your doctor or pharmacist if you notice any of these side effects:
Not Known (frequency cannot be estimated from the available data):
- increased blood sugar levels (if you are diabetic, you may need adjust your dose of insulin)
- headache, dizziness, pins and needles, drowsiness
- feeling faint on standing (postural hypotension), purple dots on the skin with fever, headache or weight loss (vasculitis)
- feeling or being sick, diarrhoea, constipation, stomach irritation, dry mouth, feeling thirsty
- sensitivity to sunlight or artificial light (e.g. sun beds)
- kidney stones, changes in the amount of urine
- inability to maintain an erection
- (shown in blood tests): increased triglycerides, increased cholesterol, low 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 magnesium and sodium levels, high levels of calcium (hypercalcaemia), low levels of chloride ions with increased alkalinity in the body (hypochloraemic alkalosis), increase in uric acid (with or without gout)

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 Bendroflumethiazide tablets
Keep out of the sight and reach of children.
Store below 25°C in a dry place.
Do not take this medicine after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.
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 Bendroflumethiazide tablets contain
- The active substance 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, impressed 'C' on one face and 'BA' on either side of the central division line on the reverse.
5mg tablets are white, circular, flat bevelled-edge, uncoated tablets, impressed 'C' on one face and 'BB' on either side of the central division line on the reverse.
Pack size is 28.

Marketing Authorisation Holder and Manufacturer
Accord, Barnstaple, EX32 8NS, UK.

This leaflet was last revised in October 2020