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 tablets, 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 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).
- 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).

Continued top of next column

Warnings and precautions
Talk to 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**).

Other medicines and Bendroflumethiazide tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. 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
- 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)
- 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.

Continued over page

Bendroflumethiazide tablets contain lactose
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 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 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 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 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, changes in the levels of salts and electrolytes in your blood and central nervous system depression (drowsiness, tiredness and coma). Treatment for overdosing involves fluid and electrolyte replacement.

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

Contact your doctor at once if you experience the following:
- **Allergic reaction** (hypersensitivity) (frequency **Not Known** - frequency cannot be estimated from the available data): 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** (frequency **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.

The following side effects have been reported under frequency Not known (frequency cannot be estimated from the available data). Tell your doctor or pharmacist if you notice any of these side effects, they get worse or you notice any not listed.
- **Metabolism:** Bendroflumethiazide may occasionally affect the level of sugar in the blood. If you are an insulin-dependent diabetic patient, you may need to have your dose of insulin adjusted as your body's ability to deal with the insulin may be affected if you are taking bendroflumethiazide at the same time; an increase in uric acid in your blood, causing gout; changes in blood lipid (fat) levels (shown in blood tests).
- **Chemicals within the body** (shown in blood tests): 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 levels of calcium in the blood (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 (which may present as jaundice – yellowing of the skin or whites of the eyes, dark urine and pale stools), 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 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 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 Contents of the pack and other 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 2019

Continued top of next column

actavis
Actavis, Barnstaple, EX32 8NS, UK