

PATIENT LEAFLET: INFORMATION FOR THE USER

BENDROFLUMETHIAZIDE 2.5 MG TABLETS
BENDROFLUMETHIAZIDE 5 MG TABLETS
(bendroflumethiazide)

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 queries, 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.
- 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
2. What you need to know before you take Bendroflumethiazide tablets
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1. What Bendroflumethiazide Tablets are and what they are used for

The name of your medicine is Bendroflumethiazide 2.5 mg tablets or Bendroflumethiazide 5mg tablets. The active ingredient is Bendroflumethiazide. 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 and **tell** your doctor if you:

- are allergic to thiazides or any of the other ingredients in Bendroflumethiazide tablets (see section 6). Allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing.
- have high levels of calcium in your blood (hypercalcaemia)
- have severe liver or kidney problems, or you are unable to pass water (urine)

- have underactive adrenal glands (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).
- 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).

Warnings and Precautions

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

- have taken high doses of Bendroflumethiazide Tablets or have taken the tablets for a long time, or if you have severe heart disease or are taking digitalis preparations (e.g. digoxin). Your doctor may decide you need to take potassium supplement tablets
- have problems with your liver or kidney
- are seriously ill
- suffer from a condition known as hyponatraemia (low blood levels of sodium), particularly if you are elderly
- have low blood levels of magnesium (hypomagnesaemia);
- have low blood levels of potassium (hypokalaemia)
- have low blood levels of calcium (hypocalcaemia)
- have high blood cholesterol level (hyperlipidaemia)
- are taking lithium
- are taking pimozone, sertinodole or thioridazine (antipsychotic medication);
- are taking sulfonamide or sulfonamide derivative drugs (medicines used to treat bacterial infections);
- become more sensitive to sunlight (photosensitivity reaction);
- suffer from pancreatitis
- are diabetic or suffer from gout
- have a condition known as systemic lupus erythematosus (an allergic condition which causes joint pain, skin rashes and fever)
- have severe asthma and are taking medicines called beta-agonists; these include salbutamol, terbutaline, formoterol and salmetrol.
- have liver disease caused by alcohol (alcoholic cirrhosis).
- have diabetes. If you are taking insulin, your doctor may need to adjust your insulin dosage.
- have an inherited disorder of the red blood pigment haemoglobin causing skin blisters, abdominal pain and brain or nervous system disorders (porphyria).
- 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 this medicine. 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.

Other medicines and Bendroflumethiazide Tablets

Taking another medicine while you are taking Bendroflumethiazide tablets can affect how it or the other medicine works. Tell your doctor if you are taking any other medicines, especially the following: This includes medicines you may have bought yourself.

- medicines used to treat high blood pressure including ACE inhibitors, (e.g. Enalapril) angiotensin-II antagonists (e.g. Losartan), alpha-blockers, such as prazosin, beta-blockers, calcium channel blockers (e.g. amlodipine and diltiazem), hydralazine, diazoxide and methyldopa
- medicines used for heart problems including amiodarone, disopyramide, flecainide, lidocaine, mexiletine, quinidine, sotalol, nitrates and cardiac glycosides (e.g. digoxin)
- dopaminergic medication e.g. levodopa (most often used to treat Parkinson's disease and restless legs syndrome)
- medicines used to treat epilepsy, such as carbamazepine
- medicines taken for depression and mental illness including tricyclic antidepressants, monoamine oxidase inhibitors (MAOIs), reboxetine, pimozone, sertindole or thioridazine, lithium and phenothiazines
- other diuretics including acetazolamide and loop diuretics
- medicines used for diabetes, such as chlorpropamide and insulin
- medicines used to treat asthma called beta-agonists
- medicines used in the treatment of gout, such as allopurinol
- medicines, called prostaglandins, such as alprostadil (a medicine used for erectile dysfunction)
- medicines used to treat fungal infections, such as amphotericin
- medicines used to treat bacterial infections, such as trimethoprim
- medicines used to treat malaria, such as halofantrine
- medicines used as dietary supplements, such as calcium salts or vitamin D
- medicines used to treat inflammation, such as cortisone and hydrocortisone (prednisolone)
- medicines used to treat stomach ulcers, such as carbenoxolone
- medicines used to treat high blood cholesterol, such as cholestyramine and colestipol
- medicines, called non-steroidal anti-inflammatory drugs (NSAIDs) used to treat pain or inflammation, such as indomethacin, ketorolac, ibuprofen, piroxicam or naproxen
- medicines, called antihistamines, used to treat allergies, such as terfenadine and astemizole
- medicines, called muscle relaxants, such as tizanidine, baclofen, tubocurarine, gallamine, alcuronium or pancuronium
- medicines used in the treatment of breast cancer, called hormone antagonists, such as toremifene
- medicines used to treat kidney and skin cancer (melanoma), such as aldesleukin
- medicines called general anaesthetics used to stop pain during surgery
- medicines used to suppress the immune system following organ transplants, such as ciclosporin.
- Medicines called sulfonylureas which are used in diabetes to control blood sugar levels
- moxislyte (used in Raynaud's syndrome)
- cisplatin (used to treat cancer)
- aminoglutethamide (used in some cancers and Cushing's syndrome)

- oestrogens and combined oral contraceptives
 - sympathomimetic medication (used to treat low blood pressure, asthma, heart failure, shock, and anaphylaxis);
 - Theophylline is a xanthine (used in breathing problems such as asthma) acetazolamide, which is used to treat glaucoma (increased pressure in the eye), epilepsy or for preventing altitude sickness
 - if you are receiving adrenocorticotrophic (ACTH) hormone
 - opioids (strong-pain relieving medicines such as codeine or diamorphine)
 - barbiturates (medicines used to treat either fits or to help you sleep e.g. phenobarbital)
- Tell your doctor if you are having or have had tests for thyroid problems.

Pregnancy, breast-feeding and fertility

If you are pregnant or thinking of becoming pregnant, check with your doctor before you use Bendroflumethiazide Tablets. Your doctor will decide if you should take them.

Do not breast-feed if you are taking Bendroflumethiazide Tablets. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Bendroflumethiazide tablets may cause dizziness, drowsiness and mental confusion. Make sure you are not affected before driving or operating machinery.

Bendroflumethiazide tablets with food, drink and alcohol

Alcohol can affect the way Bendroflumethiazide Tablets work. During treatment with Bendroflumethiazide Tablets, talk to your doctor before consuming alcoholic drinks.

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. Bendroflumethiazide may interfere with a number of laboratory tests including estimation of serum protein-bound iodine and tests of parathyroid function.

Bendroflumethiazide Tablets contain Lactose

This medicine contains **lactose**. If you have been previously told by your doctor that you have intolerance to some sugars (such as lactose) contact your doctor before taking this medicinal product.

3. How to take Bendroflumethiazide Tablets

- Always take this medicine exactly as advised by your doctor. You should check with your doctor or pharmacist if you are not sure.
- The number of tablets you need will depend on your condition.
- Swallow the tablets **with water in the morning** (to avoid frequent urination at night).

Doses:**Adults and children 12 years and over:**

- **High blood pressure:** 2.5 mg to 5 mg once a day.
- **Oedema:** Initially 5-10mg once a day or once every other day. The maintenance dose is 5-10mg one to three times a week.

Elderly:

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

Children under 12 years:

A more appropriate formulation may be used. Initially 400micrograms per kilogram of body weight a day. The maintenance dose is 50-100 micrograms per kilogram of body weight, a day.

If you take more Bendroflumethiazide Tablets than you should

If you accidentally take too many tablets, tell your doctor immediately or contact your nearest Hospital Casualty/ Accident and Emergency Department even if there are no signs of discomfort. Take your medicine in its original packaging with you in order to enable the doctor to identify your medication easily. Symptoms of an overdose include feeling or being sick, diarrhoea, dehydration, dizziness, weakness, fits (seizures) 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), magnesium (hypomagnaesia), calcium (hypocalcaemia) and sodium (hyponatraemia), low or increased blood sugar levels (hypoglycaemia or hyperglycaemia) 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 or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you notice any of these problems **talk to your doctor straight away:**

Rare (may affect up to 1 in 1,000 people):

- Blood disorders: altered numbers and types of blood cells. If you feel very tired, experience unexpected bruising or bleeding, or more infections (e.g. colds and sore throats) than usual, please tell your doctor immediately. Your doctor may decide to conduct tests on your blood periodically as a result of these symptoms
- Inflammation of the pancreas, which causes severe pain in the abdomen.

Not Known (frequency cannot be estimated from the available data):

- Allergic reaction (hypersensitivity): skin rashes, severe skin reactions, which include swelling of the face, lips, tongue and/or throat which may be accompanied by difficulty in swallowing or breathing; sensitivity to sunlight or artificial light (e.g. sun beds) inflammation of the lungs (pneumonitis) or fluid retention on the lungs (pulmonary oedema)

- 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):
- Joint pain, tiredness, or skin rashes (lupus)

Other side effects may include:**Not Known (frequency cannot be estimated from the available data):**

- Bendroflumethiazide may occasionally increase the level of sugar in the blood; and can aggravate or cause diabetes.
- Headache, dizziness, a tingling or prickling sensation ‘pins and needles’, drowsiness:
- Dizziness or faintness on standing which may be due to a lowering of your blood pressure.
- Inflammation of blood vessels, often with skin rash (vasculitis)
- Nausea, vomiting, diarrhoea, and constipation: 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.
- Blockage within the liver, which causes itching, yellowing of the skin or whites of the eyes (jaundice), dark urine and pale stools.
- Inflammation of the gallbladder and gallstones.
- Inflammation of the kidneys, kidney stones and decreased urine output.
- Inability to maintain an erection, (reversible once your treatment with Bendroflumethiazide Tablets is over or stopped)
- Signs and symptoms of chemical/salt imbalance such as dry mouth, thirst, weakness, lethargy, drowsiness, restlessness and anxiety, muscle pain and cramps, seizures, changes in heart rate and blood pressure, diarrhoea, and gastro-intestinal problems.
- Change in blood lipid (fat) levels.
- A decrease in blood levels of potassium, which may cause increased frequency and volume of urination, a feeling of discomfort or unease, muscle weakness or cramp, dizziness, feeling or being sick and loss of appetite.
- A decrease in blood levels of sodium or magnesium.
- An increase in blood levels of calcium.
- Low blood levels of chloride ions with increased alkalinity in the body (hypochloraemic alkalosis)
- A rise in the level of uric acid in the blood which can result in swelling of the joints (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 Website : 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

- Containers and blister carton: Do not store above 25°C.
- Store in the original packaging and keep the packaging tightly closed in order to protect the tablets from light and moisture.
- Do not use this medicine after the expiry date which is stated on the carton. 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. This is the new name for bendrofluazide. The ingredient itself has not changed.
- Bendroflumethiazide Tablets come in two strengths 2.5mg and 5mg. Each tablet contains either 2.5mg or 5mg of the active ingredient.
- The other ingredients are: lactose, pregelatinised starch, talc and stearic acid.

What Bendroflumethiazide Tablets look like and contents of the pack.

- Bendroflumethiazide 2.5 mg Tablets are white to almost white circular, biconvex, uncoated tablets.
- Bendroflumethiazide 5 mg Tablets are white to almost white, circular, flat, beveled edged, uncoated tablets with ‘5’ debossed on one side.
- Bendroflumethiazide Tablets come in blister packs containing 14, 28, 56 or 84 tablets and containers containing 50, 100, 250, 500 or 1000 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Bendroflumethiazide 2.5 mg tablets; PL 17907/0082

Bendroflumethiazide 5 mg tablets; PL 17907/0083

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