

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 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.

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
3. How to take Bendroflumethiazide Tablets
4. Possible Side Effects
5. How to store 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 5 mg tablets. The active ingredient is bendroflumethiazide.

Bendroflumethiazide tablets belong to a group of medicines called thiazide diuretics (water tablets).

Diuretic medicines are those that promote the excretion of urine.

Bendroflumethiazide Tablets are used to treat hypertension (high blood pressure) and oedema (fluid retention). They are also used to stop the production of breast milk.

2. What you need to know before you take Bendroflumethiazide tablets

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

- you ever had an allergic reaction to bendroflumethiazide or any other ingredients of this medicine (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);
- you suffer from an imbalance of water and salts in the body;
- you suffer from hypercalcaemia (high levels of calcium in the blood);
- you suffer from elevated levels of uric acid in the blood (hyperuricaemia);
- you have severe liver or kidney problems;
- you suffer from Addison's disease.

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before taking Bendroflumethiazide tablets if:

- you suffer from gout;
- you are diabetic;
- you suffer from or have a history of a condition called systemic
- lupus erythematosus;

- you suffer from alcoholic cirrhosis;
- you suffer from mild to moderate kidney or liver disease as your doctor may wish to monitor you more frequently.
- If you 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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Especially:

- medicines for relieving pain and inflammation e.g. non-steroidal anti-inflammatory drugs;
- ACTH (corticotropin), acetazolamide (used to treat glaucoma) or carbenoxolone (used to treat ulcers);
- medicines used to reduce inflammation e.g. corticosteroids;
- any other medicine for high blood pressure (including other diuretics and alpha blockers such as prazosin);
- medicines known as barbiturates (these are used to treat a range of conditions from severe insomnia to epilepsy) e.g. phenobarbital;
- medicines used to treat pain that contain opioids such as codeine or diamorphine;
- medicines for treating epilepsy e.g. carbamazepine;
- medicines for treating infections e.g. amphotericin;
- calcium salts or vitamin D preparations;
- medicines for treating cancer (particularly cisplatin, toremifene or aminoglutethimide);
- medicines for treating irregular heart beats e.g. disopyramide, amiodarone, flecainide, quinidine, lidocaine, mexiletine or calciumchannel blockers e.g. nicardipine (used to treat heart problems);
- medicines which provide contraception e.g. oral contraceptives;
- medicines for treating asthma e.g. theophylline;
- medicines used to treat allergies e.g. terfenadine;
- a medicine called moxislyte, which is used to treat Raynaud's syndrome;
- medicines like pimozide or thioridazine used to treat psychoses (the term used to describe a broad range of conditions affecting a person's mental state, often characterised by symptoms such as delusional thoughts, hallucinations and agitated behaviour)
- medicines used to treat depression (including lithium, a medicine called reboxitene or a class of medicines known as mono amineoxidase inhibitors);
- medicines used to treat a condition known as multiple sclerosis or spinal injuries (e.g. baclofen and tizanide).

Other special warnings

- Be careful when drinking alcohol - it may affect you more than usual.
- If you see another doctor or visit a hospital, remember to tell them what medicines you are already taking.
- If you are going to have an operation please tell the anaesthetist that you are taking Bendroflumethiazide 2.5 mg and 5 mg Tablets as this may affect some of the drugs he/she may use.

- If you are being treated for depression with tricyclic antidepressants e.g. amitriptyline, there may be an increased risk of postural hypotension (fall in blood pressure) whilst taking Bendroflumethiazide Tablets.
- Colestipol and colestyramine may reduce the absorption of thiazide diuretics and should therefore be given 2 hours prior to, or after the ingestion of bendroflumethiazide.
- Your doctor may wish to monitor you regularly and carry out blood tests while you are taking this treatment. This may be the case especially if you are elderly or are taking the medicine long term.

Pregnancy, breast-feeding and fertility

Bendroflumethiazide tablets should not be used in pregnant or breastfeeding women. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

Bendroflumethiazide should not normally affect your ability to drive or operate machinery. If you find that you get dizzy or drowsy, do not drive or operate machinery.

Bendroflumethiazide tablets with food, drink and alcohol

It is recommended not to take alcohol with Bendroflumethiazide tablets as it may aggravate dizziness on standing due to low blood pressure.

Bendroflumethiazide Tablets contain 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 medicine.

3. How to take Bendroflumethiazide Tablets

Always take your medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. He or she will tell you how many to take and how often to take them. The doses commonly prescribed are listed below. Your doctor may prescribe different doses depending on your needs.

High blood pressure:

The usual dose is 2.5 mg taken once daily in the morning. Higher doses are rarely necessary.

Fluid retention:

The usual starting dose is 5 to 10 mg once daily or every other day.
The usual maintenance dose is 5 to 10 mg one to three times weekly.

Suppression of breast milk:

The usual dose is 5 mg taken in the morning and 5 mg taken at midday.
Treatment usually lasts for approximately five days.

Children:

The dose in children depends on how much they weigh. The starting dose is up to 400 micrograms per kilogram of body weight. The maintenance dose is 50-100 micrograms per kilogram of body weight. Your doctor will tell you how many tablets your child will have to take.

Elderly:

The dose of Bendroflumethiazide Tablets may need to be reduced in some elderly patients when there is the possibility of salt imbalance in the blood. It is important that you keep taking these tablets until your doctor tells you to stop. Do not stop just because you feel better. If you stop taking the tablets too soon your condition may get worse.

If you take more tablets than you should

If you accidentally take too much of your medicine, you should contact a doctor immediately or go to the nearest hospital casualty department.

Take your medicine and this leaflet with you.

If you forget to take your medicine

If you forget to take a dose, just take the next dose at the usual time, DO NOT take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines Bendroflumethiazide 2.5 mg and 5 mg Tablets can cause unwanted side effects in some people, although it is generally well tolerated. You are unlikely to get any of the following, but if you do, tell your doctor immediately:

- Hypersensitivity reactions (including severe skin reactions, which include swelling of the face, lips, tongue and/or throat which may be accompanied by difficulty in swallowing or breathing; inflammation of the lungs (pneumonitis) or fluid retention on the lungs (pulmonary oedema))
- 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.
- 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)

Other side effects may include:

- Skin rashes, sensitivity to light, blood disorders of various types including anaemia;
- A rise in the level of uric acid in the blood which can result in swelling of the joints (gout) may occur;
- Problems with the pancreas and liver have been reported;
- Like other water tablets, Bendroflumethiazide may occasionally affect the level of sugar in the blood;
- Dizziness or faintness on standing which may be due to a lowering of your blood pressure;
- Impotence has been reported occasionally, although this is reversible once your treatment with Bendroflumethiazide Tablets is over or stopped;
- 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 may be signs and symptoms of salt imbalance. This is caused by a lowering of the levels of potassium or sodium 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.
- High level of calcium in the blood.

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 to HPRAs Website: www.hpra.ie, e-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bendroflumethiazide Tablets

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Do not use this medicine after the expiry date which is stated on the carton after EXP.. 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.
- Bendroflumethiazide Tablets come in two strengths 2.5 mg and 5 mg. Each tablet contains either 2.5 mg or 5 mg 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, bevelled edged, uncoated tablets with '5' debossed on one side.
- Bendroflumethiazide Tablets come in blister packs containing 14, 28, 56 or 84 tablets. Not all pack sizes may be marketed.

Marketing authorisation Holder

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