

Title: Bendroflumethiazide
Tablets PIL

Ref: RX/BEN

Date: 24/02/18
(Modified) 04/01/21

Size (mm):
345(H) x 170(W)

Colours (Printed)



Colours (NOT Printed)



Typefaces:

BODY COPY
Swiss Roman - 8pt

SMALL SUB HEADINGS
Swiss Bold - 8pt

NUMBERED HEADINGS
Swiss Heavy - 11pt

Front of leaflet - 345mm

Package leaflet: Information for the Patient

BENDROFLUMETHIAZIDE 2.5MG TABLETS BENDROFLUMETHIAZIDE 5MG TABLETS (Bendroflumethiazide)

This medicine will be called Bendroflumethiazide
Tablets in this leaflet.

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, pharmacist or nurse.
- This medicine is only for you. Do not pass it to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any of the side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Bendroflumethiazide Tablets is and what it is 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
6. Contents of the pack and other information

1. What Bendroflumethiazide Tablets is and what it is used for

These tablets are available in two different strengths, 2.5mg and 5mg and your doctor will have decided which is the most suitable for you.

Bendroflumethiazide belongs to a group of medicines called diuretics (water tablets) which increase urine production. Bendroflumethiazide Tablets are used to treat hypertension (high blood pressure) and oedema (fluid retention) associated with such conditions as kidney disorder, liver damage, heart failure and premenstrual fluid retention.

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

Do not take Bendroflumethiazide Tablets:

- 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);
- if you suffer from an imbalance of water and salts in the body;
- if you suffer from hypercalcaemia (high levels of calcium in the blood);
- if you suffer from elevated levels of uric acid in the blood (hyperuricaemia);
- if you have low levels of potassium in the blood (hypokalaemia) which has not responded to treatment;
- if you have severe liver or kidney problems;
- if you suffer from Addison's disease.
- if you are lactose intolerant.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Bendroflumethiazide Tablets

- if you suffer from gout;
- if you are diabetic;
- if you suffer from or have a history of a condition called systemic lupus erythematosus;
- if you have low levels of potassium in the blood (hypokalaemia);
- if you have low levels of sodium in the blood (hyponatraemia);
- if you have low levels of magnesium in the blood (hypomagnesaemia);
- if you are taking lithium;
- if you have high levels of calcium in the blood (hypercalcaemia);
- if you are taking pimozide, sertindole or thioridazine (antipsychotic medication);
- if you are taking sulfonamide or sulfonamide derivative drugs (medicines used to treat bacterial infections);
- if you suffer from alcoholic cirrhosis;
- if you become more sensitive to sunlight (photosensitivity reaction);
- if you have high cholesterol levels;
- if 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 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.

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.

- antidiabetics e.g. insulin
- antimalarials e.g. halofantrine
- antibacterials e.g. trimethoprim
- digitalis glycosides e.g. digoxin (used to treat mild to moderate heart failure)
- diuretics
- aldesleukin (used in immune therapy)
- alprostadil (a medicine used for erectile dysfunction)
- dopaminergic medication e.g. levodopa (most often used to treat Parkinson's disease and restless legs syndrome)
- chlorpropamide (a medicine used to treat diabetes)
- medicines for relieving pain and inflammation (non-steroidal anti-inflammatory drugs) e.g. indomethacin, ketorolac, ibuprofen, piroxicam and naproxen
- ACTH (corticotropin), acetazolamide (used to treat glaucoma) or carbenoxolone (used to treat ulcers)
- medicines used to reduce inflammation e.g. corticosteroids
- muscle relaxants, e.g. tubocurarine, gallamine, alcuronium and pancuronium
- 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;
- general anaesthetics
- medicines for treating epilepsy e.g. carbamazepine
- nitrates (used to treat angina); medicines for treating fungal infections e.g. amphotericin
- calcium salts or vitamin D preparations
- medicines for treating cancer e.g. toremifene, cisplatin and aminoglutethimide
- immunosuppressive agents e.g. ciclosporin
- medicines for treating irregular heart beats e.g. disopyramide, amiodarone, flecainide, quinidine, lidocaine, mexiletine or calcium-channel blockers e.g. nifedipine (used to treat heart problems)
- oestrogens and combined oral contraceptives
- medicines for treating asthma e.g. theophylline
- medicines used to treat allergies e.g. terfenadine and astemizole
- a medicine called Moxisylyte, which is used to treat Raynaud's syndrome
- medicines like pimozide, sertindole 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 e.g. reboxitene, or a class of medicines known as monoamine oxidase inhibitors. Tricyclic antidepressants e.g. amitriptyline (there may be an increased risk of fall in blood pressure).
- lithium
- medicines used to treat high blood pressure, including ACE inhibitors and methyldopa. Alpha blockers such as prazosin.
- medicines used to treat a condition known as multiple sclerosis or spinal injuries (eg. baclofen and tizanide)
- sympathomimetic medication (used to treat low blood pressure, asthma, heart failure, shock, and anaphylaxis); 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.

Bendroflumethiazide Tablets with food, drink and alcohol

Tell your doctor before taking this medicine if you have been told that you have intolerance to some sugars. This is because Bendroflumethiazide 2.5 mg and 5 mg Tablets contain a small amount of lactose, a type of sugar. Drinking alcohol may affect you more than usual.

Other special warnings

- If you have to take the tablets for a long time you may also have to take potassium supplement tablets.
- 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 Tablets as this may affect some of the drugs he/she may use.

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- 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

Tell your doctor if you become pregnant, or are breast feeding.

Driving and using machines

Bendroflumethiazide should not normally affect your ability to drive or operate machinery. If you find that you do get drowsy, do not drive or operate 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 this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

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 2.5mg to 5mg two or three times weekly.

Use in 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. The score line is not intended for breaking the tablet.

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 Bendroflumethiazide 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 Bendroflumethiazide Tablets

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.

If you get any of the following serious side effects, stop taking Bendroflumethiazide and contact your doctor or emergency department immediately:

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 (hypochloreaemic alkalosis)
- A rise in the level of uric acid in the blood which can result in swelling of the joints (gout).

Reporting 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 this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister, carton. The expiry date refers to the last day of that month.
- Do not use this medicine if you notice the tablets show signs of "going off" such as discoloration.
- The tablets should not be stored above 25°C. The tablets should be kept in the package in which they were given to you. Do not transfer your tablets to another container.
- 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 contains

Bendroflumethiazide Tablets contain the active ingredient bendroflumethiazide.

The other ingredients are lactose monohydrate, pregelatinised maize starch, maize starch, purified talc and magnesium stearate.

What Bendroflumethiazide Tablets looks like and contents of the pack

Bendroflumethiazide 2.5mg Tablets are white, circular, flat faced tablets with bevelled edges, B 2.5 separated by a breakline on one side and plain on the reverse.

Bendroflumethiazide 5mg Tablets are white circular, flat faced tablets with bevelled edges, B 5 separated by a break line on one side and plain on the reverse.

Bendroflumethiazide 2.5mg and 5mg Tablets are available in blister packs of 28 tablets.

Marketing Authorisation Holder: RxFarma, Colonial Way, Watford, Hertfordshire, WD24 4YR. United Kingdom

Manufacturer: RX Farma Limited, Unit 3, Colonial Way, Watford, Hertfordshire, WD24 4YR, United Kingdom

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Date of Revision: January 2021.