Package leaflet: Information for the user

BENDROFLUMETHIAZIDE  
2.5 & 5 mg 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 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 is and what it is used for
2. What you need to know before you take Bendroflumethiazide
3. How to take Bendroflumethiazide
4. Possible side effects
5. How to store Bendroflumethiazide
6. Contents of the pack and other information

1. What Bendroflumethiazide is and what it is used for
Bendroflumethiazide tablet contains an active substance called bendroflumethiazide which belongs to group of medicines known as the thiazide diuretics. It may be used to treat:
- reduce fluid retention (oedema) particularly in the heart, kidneys, liver or that caused by medication, by increasing the flow of urine
- reduces high blood pressure alone or with other medication

You must talk to your doctor if you do not feel better or if you feel worse

2. What you need to know before you take Bendroflumethiazide
Do not take Bendroflumethiazide Tablets:
- If you have ever had any unusual or allergic reactions to Bendroflumethiazide or any of the other ingredients of this medicine (listed in section 6) or other thiazide diuretics.
- If you have severe liver or kidney problems
- If you have low blood levels of potassium or sodium
- If you have high blood levels of calcium
- 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).
- 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 if you have
- Kidney or liver disease,
- Diabetes
- porphyria (an inherited iron disorder) or have gout (increased serum levels of uric acid)
- have Systemic Lupus Erythematosus (an inflammatory disease which causes joint pain, weight loss, skin rashes and fever)
- blood related diseases or inflammation of pancreas
- Liver disease caused by alcohol (alcoholic cirrhosis)
- An intolerance to some sugars, including lactose
- If you are receiving digitalis treatment.
- Patients taking pimozide or thioridazine

Other Medicines and Bendroflumethiazide Tablets
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

Check with your doctor if you are taking:
- Allopurinol (to treat gout)
- Carbenoxolone (used to treat stomach ulcers)
- Medicines to treat high blood pressure, heart disease or chest pain such as captopril, enalapril (ACE inhibitors), doxazosin, prazosin (alpha-blockers), candesartan, losartan (angiotensin-II receptor antagonists), propranolol, atenolol (beta-blockers), amiodipine, moxisylyte (calcium-channel blockers), glyceryl trinitrate, isosorbide mononitrate (nitrates) or digoxin
- Anti-arrhythmic medicines (to treat irregular heart beat) such as disopyramide, amiodarone, quinidine, lidocaine, mexiletine or flecainide
- Colestipol and colestyramine (to lower cholesterol)
- Alprostadil (for problems maintaining an erection)
- Levodopa (to treat parkinson’s disease)
- Carbamazepine (to control epilepsy)
- Lithium or medicines for mental health problems such as sertindole, pimozide or thioridazine
- Medicines for depression such as reboxetine, tricyclic antidepressants or monoamine oxidase inhibitors (MAOIs)
- Medicines known as non-steroidal anti-inflammatory drugs (for example aspirin, ibuprofen, indometacin and ketorolac), used to treat pain and inflammation
- Aldesleukin, amino-glutethimide, cisplatin and toremifene (anti-cancer drugs)
- Oestrogens (female hormone treatment / contraceptive)
- Antidiabetics (to reduce blood sugar levels), such as sulfonylureas
- Acetazolamide (to treat glaucoma)
- Amphotericin (to treat fungal infections)
- Muscle relaxants such as baclofen or tizanidine, tubocurarine, gallamine, alcuronium or pancuronium
- Theophylline and beta2 sympathomimetics (for asthma)
- Corticosteroids such as prednisolone (for treatment of inflammation or allergies) and ACTH
- Vitamin D and calcium salts
- Patients taking pimozide or thioridazine

Bendroflumethiazide with food, Drink and Alcohol
Alcohol should be avoided when taking this medicine.

Pregnancy, breast feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Bendroflumethiazide.
Bendroflumethiazide should be avoided during pregnancy, as there is not sufficient evidence of its safety. Because Bendroflumethiazide passes into the breast milk it should be avoided in mothers who wish to breast-feed.
Newborn infants whose mothers have taken Bendroflumethiazide during pregnancy may
suffer from a blood condition known as thrombocytopenia.

Driving and using machines
Bendroflumethiazide tablets can cause dizziness, you should ensure you are not affected before attempting to drive or operate machinery.

Urizide tablets contains lactose
If you know you have an intolerance to lactose or other sugars, contact your doctor before taking this medicine.

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

Take this medicine by mouth and only in the doses prescribed by your doctor. Do not take more of it, and do not take it more often or for a longer time than your doctor ordered. You may be prescribed the lowest dose necessary to control your symptoms. Swallow the tablets with water in the morning (to avoid frequent urination at night) If you are elderly and/or on long term treatment, you will need regular blood tests, in particular for blood potassium levels.

Recommended doses

Adults and children 12 years and over:
Oedema: 5 mg given orally once daily, or on alternate days in the morning. This dose can be increased to 10 mg if required.
Maintenance: 2.5-10mg two or three times weekly
Essential Hypertension (high blood pressure): 2.5 - 5 mg once daily in the morning. Your doctor may prescribe a higher dose if necessary.

Children under 12 years: Initially 400 micrograms per kilogram of body weight, a day. The maintenance dose is 50-100 micrograms per kilogram of body weight, a day
A more appropriate formulation may need to be used.

Elderly: Particular caution is needed in the elderly, as they are more susceptible to the side effects. Your doctor may prescribe a reduced dose, especially if you suffer from kidney failure.

If you take more Bendroflumethiazide Tablets than you should
If you accidentally take more tablets than recommended contact your nearest doctor or hospital casualty department at once. Take any remaining tablets with you and keep in the original container or packaging so that they can be identified. Symptoms of an overdose can include feeling or being sick, diarrhoea, dehydration, dizziness, weakness, muscle cramps, increased frequency and volume of urination, thirst, decreased volumes within blood vessels, low blood pressure, circulation problems, low blood levels of potassium and sodium, low blood sugar levels and central nervous system depression (drowsiness, tiredness or coma).

If you forget to take Bendroflumethiazide
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 double dose to make for forgotten dose
If you feel that this medicine is not working as well after you have taken it for a short time (1-2 weeks) do not increase the dose, instead check with your doctor.
If you stop taking Bendroflumethiazide
If you have any further questions on this medicine, ask your doctor or pharmacist

4. Possible Side effects
Like all medicines, Bendroflumethiazide can cause side effects, although not everybody gets them.
If you get any of the following serious side effects, stop taking Bendroflumethiazide and tell your doctor or go to the nearest hospital emergency department immediately:

- An allergic reaction which may cause skin rashes, itching, sensitivity to sunlight, a viral infection of the lungs (pneumonitis) or fluid in the lungs (pulmonary oedema)
- Blood disorders which may cause you to have unexplained bleeding, bruising and sore throats. Regular blood and urine tests may be needed.

The following side effects may be experienced:
- Nausea, vomiting, diarrhoea, constipation, stomach irritation
- Some patients may experience impotence (inability to perform the sexual function). This is reversible upon stopping treatment.
- Inflammation of the pancreas may occur, which causes severe pain in the abdomen and back
- In some patients there is an increase in uric acid levels in the blood, with or without the development of gout.
- A fall in blood pressure when changing from a lying or sitting position to a standing up position, (postural hypotension), which causes dizziness, light-headedness or fainting
- A decrease in blood levels of potassium, which may cause increased frequency and volume of urination, a feeling 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
- An increase in blood sugar and worsening of diabetes
- Low blood levels of chloride ions with increased alkalinity in the body (hypochloraemic alkalosis)
- Decreased carbohydrate tolerance
- Altered concentration of lipids (fats)
- Blockage within the liver, which causes itching, yellowing of the skin or whites of the eyes (jaundice), dark urine and pale stools
- Liver disorder

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

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

5. How to Store Bendroflumethiazide
Keep this medicine out of the sight and reach of children
Do not store above 25°C. Keep the container tightly closed in order to protect from moisture.
Store in the original container in order to protect from light.
Do not use the tablets after the expiry date, which is stated on the carton and blister packs.
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 to protect the environment.

6. Contents of the pack and other information

What Bendroflumethiazide Tablet contains
The active ingredient is Bendroflumethiazide.
Each tablet contains 2.5mg and 5 mg of Bendroflumethiazide

The other ingredients are lactose, maize starch, pregelatinised starch, sodium starch glycollate, magnesium stearate.

What Bendroflumethiazide looks like and contents of the pack

2.5 mg Tablets are white, round and plain tablets
5 mg Tablets are white, round and plain tablets

Bendroflumethiazide is available in tablets in strengths of 2.5 mg and 5 mg, and in pack sizes of 28, 30, 50, 56, 60, 84,100, 250, 500 and 1000.

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