Package leaflet: Information for the user
Bendroflumethiazide 2.5mg Tablets
Bendroflumethiazide 5mg Tablets
Bendroflumethiazide (Referred to as Bendroflumethiazide Tablets in the remainder of the 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, please 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
The name of your medicine is Bendroflumethiazide Tablets. The active ingredient in your medicine is bendroflumethiazide.
Bendroflumethiazide Tablets belong to a group of medicines called diuretics (water tablets) which increase the amount of urine you produce.

Bendroflumethiazide Tablets are used to treat high blood pressure (hypertension) and fluid retention (oedema) associated with kidney, liver or heart problems.

2. What you need to know before you take Bendroflumethiazide tablets
Do not take Bendroflumethiazide Tablets if you:
- are allergic to bendroflumethiazide, or other sulphonamide-derived medicine or any of the other ingredients of this medicine (listed in section 6).
- 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)
- have low levels of sodium in your blood (refractory hypokalaemia)
- have low levels of potassium in your blood (hyponatraemia)

Warnings and precautions
Talk to your doctor, pharmacist, or nurse before taking Bendroflumethiazide Tablets
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.

Take special care with 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 kidneys
- suffer from a condition known as hyponatraemia (low blood levels of sodium)., particularly if you are elderly.
- have low blood levels of magnesium
- 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).
- suffer from alcoholic cirrhosis;
- suffer from pancreatitis

If you are elderly or have taken Bendroflumethiazide Tablets for a long time, your doctor will perform regular blood tests to check the levels of electrolytes (salts) in your blood.

Other medicines and Bendroflumethiazide Tablets

Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. The following medicines and products can affect or be affected by treatment with Bendroflumethiazide Tablets:

- drinking alcohol when being treated with Bendroflumethiazide Tablets may cause your blood pressure to drop, making you feel dizzy or lightheaded, especially when standing up (orthostatic or postural hypotension)
- medicines used to treat high blood pressure including ACE inhibitors, angiotensin-II antagonists, alpha-blockers, such as prazosin, beta-blockers, calcium channel blockers, hydralazine, diazoxide and methyldopa
- medicines used for treating irregular heartbeats and other heart problems including amiodarone, disopyramide, flecainide, lidocaine, mexiletine, quinidine, sotalol, nitrates and cardiac glycosides
- medicines used to treat Parkinson's disease, such as levodopa
- medicines used to treat epilepsy, such as carbamazepine
- medicines taken for depression and mental illness including tricyclic antidepressants, monoamine oxidase inhibitors (MAOIs), reboxetine, pimozide, sertindole, lithium, barbituates 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, such as theophylline. Theophylline in combination with bendroflumethiazide can increase the risk of hypokalaemia if used concomitantly.
- medicines used in the treatment of gout, such as allopurinol
- medicines, called prostaglandins, such as alprostadil
- medicines used to treat fungal infections, such as amphotericin
- medicines used to treat bacterial infections, such as trimethoprimmedicines

- 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
- medicines used to treat stomach ulcers, such as carbenoxolone
- medicines used to treat high blood cholesterol, such as colestyramine and colestipol. 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.
- medicines, called non-steroidal anti-inflammatory drugs (NSAIDs) used to treat pain or inflammation, such as indometacin
- medicines, called antihistamines, used to treat allergies, such as terfenadine and astemizole
- medicines called muscle relaxants, such as tizanidine
- medicines used in the treatment of breast cancer, such as cisplatin. Cisplatin can lead to an increased risk of toxicity in the kidneys (nephrotoxicity) and ear (ototoxicity)
- medicines used to treat advanced renal cell carcinoma such as aldesleukin. As an increase in low blood pressure may occur when diuretics are given with 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 opioids, used to treat chronic pain conditions.
- medicines containing oestrogen and progestogens, including combines oral contraceptives.
- medicines which are hormone antagonists such as aminoglutethimide
- medicines called vasodilators such as moxisylyte
- Sympathomimetics used for treating heart problems can cause hypokalaemia.

Tell your doctor if you are having or have had tests for thyroid problems.

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.

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 tools or machinery.

Bendroflumethiazide Tablets contains lactose
This medicine contains lactose (a type of sugar). If you have been told by your doctor that you cannot tolerate some sugars, contact your doctor before taking this medicine.

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.

Fluid retention
Adults and children aged 12 years and over: Your starting dose will be between two and four 2.5mg Bendroflumethiazide Tablets (or one to two 5mg Bendroflumethiazide Tablets) taken in the morning. The dose will then be kept at one 2.5mg tablet (or one 5mg tablet) a day on two to three days a week.

Your doctor will assess your condition and may decide that a single dose is enough.

Children under 12 years: The dose given will depend on the size of your child. Your doctor will determine the suitable dose based on the weight of your child. The usual dose is 400µg/kg body weight every day to start with.
Your doctor will assess your child's condition and may decide to reduce their dose to 50µg-100µg/kg body weight.

High blood pressure
Adults: The usual dose is one 2.5mg tablet a day taken in the morning.

Older People: You may need to take less than the usual adult dose. Your doctor will decide how many tablets you should take.

If you take more Bendroflumethiazide Tablets than you should
If you accidentally take too many tablets, you should contact your doctor or go to your nearest hospital casualty department immediately. Take this leaflet and any unused tablets with you to show the doctor.
Symptoms of an overdose include anorexia, feeling sick, being sick, diarrhea, thirst, low blood pressure, dizziness, weakness, muscle cramps, fits, increase in the frequency and amount of urination and changes in the levels of salts and electrolytes in your blood and involuntary contraction of muscles. Treatment for overdosing involves fluid and electrolyte replacement.

If you forget to take Bendroflumethiazide Tablets
If you forget to take your medicine take it as soon as you remember. If it is almost time for your next dose do not take the missed dose at all. NEVER take a double dose to make up for the one missed.

If you stop taking Bendroflumethiazide Tablets
You may experience a skin rash, itchy skin or your skin may be more sensitive to sunlight than normal if you stop taking Bendroflumethiazide Tablets. Speak to your doctor if you notice these symptoms. Do not stop taking your medicine unless your doctor tells you to. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

- severe allergic reaction (anaphylaxis). The signs of an allergic reaction may include rash, itching, difficulty breathing and/or swelling of your lips, face, throat or tongue
- inflammation of the lungs that can cause a cough or shortness of breath
- fluid in the lungs that can cause you to cough up blood and make it difficult for you to breathe
- serious skin condition with blistering of the skin
- feeling sick (nausea) or being sick (vomiting)
- loss of appetite
- feeling dizzy or lightheaded, especially when standing up (low blood pressure)
- feeling weak, tired, drowsy or sleepy
- feeling confused
- muscle cramp
- sudden headache
- fits (seizures)
- skin rash caused by exposure to light (photosensitivity).
- severe stomach pain which may reach through to your back (pancreatitis)
- pale stools, dark urine, yellowing of the skin or eyes (jaundice)

Other side effects that may be experienced while taking this medicine are:

- tingling or numbness in the hands or feet
- constipation
- diarrhoea
- dry mouth and thirst
- inflammation of blood vessels, often with skin rash (vasculitis)
- an increase in uric acid in your blood (gout)
- being unable to achieve an erection (impotence)
- reduced sexual desire
- diabetes
- changes in the salts and electrolytes in your blood (shown in blood tests)
- an increase in the levels of certain types of lipids and cholesterol in your blood (shown in blood tests)
- inflammation of the kidney which can cause you to have a fever or to pass more or less urine than normal
- severe pain in the lower back or sides (kidney stones)
- high level of calcium in the blood
- 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)

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 national reporting systems listed below:

United Kingdom:
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Malta:
ADR Reporting, Website:
www.medicinesauthority.gov.mt/adrportal

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 Bendroflumethiazide Tablets after the expiry date which is stated on the blister and carton.
The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original 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 contain
The active ingredient is bendroflumethiazide.

Each Bendroflumethiazide 2.5mg Tablet contains 2.5mg of bendroflumethiazide.

Each Bendroflumethiazide 5mg Tablet contains 5mg of bendroflumethiazide.

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

What Bendroflumethiazide Tablets look like and contents of the pack
Bendroflumethiazide 2.5mg Tablets are white, circular flat faced tablets with bevelled edges, marked CP on one side and B 2.5 separated by a breakline on the other side.

Bendroflumethiazide 5mg Tablets are white, circular flat faced tablets with bevelled edges, marked CP on one side and B 5 separated by a breakline on the other side.

Bendroflumethiazide 2.5mg Tablets are available in the following packs:

- 500 tablets in polypropylene or polyethylene containers.

Bendroflumethiazide 5mg Tablets are available in the following packs:
- 50 tablets in amber glass bottles with a plastic cap
- 100, 250, 500 and 1000 and bulk amount of tablets in polypropylene or polyethylene containers.

Both strengths of tablets are available in the following packs:
- 10, 14, 20, 28, 30, 40, 50, 56, 60, 70, 80, 84, 90, 100 or 112 tablets in blister packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Austin McNeil Ltd.,
772 Fulham Road, London,
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Manufacturer
CP Pharmaceuticals Ltd
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