Package leaflet: Information for the patient

Abendur 2.5 mg Tablets

Abendur 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 questions, ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet (See section 4).

What is in this leaflet:

1. What Abendur Tablets is and what it is used for
2. What you need to know before taking Abendur Tablets
3. How to take Abendur Tablets
4. Possible side effects
5. How to store Abendur Tablets
6. Contents of the pack and other information

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

The name of your medicine is Abendur Tablets. The active ingredient in your medicine is bendroflumethiazide.

Abendur Tablets belong to a group of medicines called diuretics (water tablets) which increase the amount of urine you produce.

Abendur Tablets are used to treat high blood pressure (hypertension) and fluid retention (oedema).

2. What you need to know before taking Abendur Tablets

Do not take Abendur tablets and tell your doctor if:

- you are allergic to Bendroflumethiazide or any other ingredients of this medicine (listed in 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);
- 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 (hormone deficiency caused by damage to the outer layer of the adrenal gland).

Warnings and precautions

Talk to your doctor, pharmacist, or nurse before taking Abendur Tablets if:

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

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, ACE inhibitors 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, digitalis glycosides, sotalol quinidine, lidocaine, mexiletine or calcium channel 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 moxisylyte, 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 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;
- 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.

Abendur 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.

Pregnancy, breast-feeding and fertility

Abendur 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.

Abendur Tablets contains Lactose

If you have been told by your doctor that you have an intolerance to some sugars (such as lactose), contact your doctor before taking this medicinal product.

3. How to take Abendur Tablets

Always take your medicine exactly as your doctor or pharmacist has told you.

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.

Adults

High blood pressure:

The usual dose is 2.5 to 5 mg taken once daily in the morning.

Fluid retention:

The usual starting dose is 5 to 10 mg once daily.

The usual maintenance dose is 2.5 to 5 mg daily continuously or intermittently with 2-4 treatment-free days per week.

Pre-menstrual fluid retention:

The usual dose is 2.5 mg daily 7-10 days premenstrually.

Elderly:

The dose of bendroflumethiazide 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 Abendur 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.

If you forget to take Abendur Tablets

If you forget to take your medicine, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking Abendur Tablets

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, Abendur Tablets can cause side effects, although not everybody gets them. 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 Abendur 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 HPRA Pharmacovigilance, Website: www.hpra.ie.

5. How to store Abendur Tablets

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date (EXP.) 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.
- 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 Abendur Tablets contain:

The active ingredient is bendroflumethiazide.

For 2.5 mg: Each Tablet contains 2.5mg of bendroflumethiazide.

For 5 mg: Each Tablet contains 5mg of bendroflumethiazide.

The other ingredients are lactose anhydrous, pregelatinised maize starch, purified talc, stearic acid.

What Abendur Tablets look like and contents of the pack

Abendur 2.5mg Tablets are white to almost white, circular, biconvex, uncoated tablets.

Abendur 5mg Tablets are white to almost white, circular, flat, bevelled edged uncoated tablets with '5' embossing on one side.

Abendur Tablets are packed in PVDC coated PVC / Aluminium blisters of 14 tablets which are placed in an outer carton. Pack size: 28 tablets.

Marketing Authorisation Holder

Ascot Laboratories (Ireland) Limited
Clarity House
Belgard Road
Tallaght
Dublin 24
D24 Y6DF
Ireland

Manufacturer

Emona Biopharma razvoj proizvodnja in prodaja d.o.o.
Dunajska cesta 156,
Ljubljana, 1000, Slovenia

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