PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Bendroflumethiazide Evolan 2.5mg tablets

Bendroflumethiazide Evolan 5mg 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 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 EVOLAN IS AND WHAT IT IS USED FOR

This medicine is a diuretic (medicine that acts over the kidney and that stimulates urine production) that belongs to the family of thiazide diuretics.

Bendroflumethiazide Evolan may be used to: treatment of oedema (swollen) associated with kidney, liver or heart problems, hypertension (high blood pressure).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BENDROFLUMETHIAZIDE EVOLAN

Do not take Bendroflumethiazide Evolan:
- if you are allergic (hypersensitive) to bendroflumethiazide or any of the other ingredients of Bendroflumethiazide Evolan;
- if you suffer from: low level of potassium (hypokalaemia), low level of sodium (hyponatraemia);
- if you suffer from impairment in kidney functioning;
- if you suffer from impairment inliver functioning;
- if you suffer from high levels of uric acid (symptomatic hyperuricaemia);
- if you suffer from Addison's disease (disease characterized by insufficient production of hormones by a gland located upper to the kidney).

Warning and precautions
Talk to your doctor or pharmacist before taking Bendroflumethiazide Evolan:
- if you have impaired kidney or liver function;
- if you have lupus erythematosus (chronic disease that destroys the cells of our organism producing inflammatory processons in several parts of the body);
- if photosensitivity reaction occurs during treatment, it is recommended to stop the treatment; if a re-administration of the diuretic is deemed necessary, it is recommended to protect exposed areas to the sun or to artificial UVA;

- if you are an elderly patient and is or will take Bendroflumethiazide Evolan for long term treatment, you should perform regular ongoing monitoring.
  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 weeks of taking Bendroflumetiazid Evolan. 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 Evolan
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

There are some medicines that can modify Bendroflumethiazide Evolan effect or that can have their effect modified by Bendroflumethiazide Evolan.

If you take Bendroflumethiazide Evolan with:
- Digitalis glycosides: Their action can be increased by hypokalaemia effect (reduction of potassium levels);
- Lithium: Lithium concentrations can be increased by use of Bendroflumethiazide Evolan or any other thiazide diuretics;
- Non-steroidal anti-inflammatory drugs: These medicines may blunt the diuretic (kidney activity) and antihypertensive effects (changes in blood pressure) of Bendroflumethiazide Evolan. This combination can increase the risk of nephrotoxicity (kidney impairment);
- Xanthines, β-agonists, ACTH, corticosteroids, acetazolamide and carbenoxolone: Bendroflumethiazide intake with these medicines may result in reduction of potassium levels;
- Tubocurarine (and other non-depolarizing muscle relaxants): Bendroflumethiazide Evolan or any other thiazide diuretic medicine may enhance the neuromuscular blocking;
- Thiazides, monoamine oxidase inhibitors (MAOIs), baclofen, tizanidine and prazosin (post-synaptic alpha-blockers): The interaction of these medicines with Bendroflumethiazide Evolan may lower blood pressure;
- Barbiturates or opioids and tricyclic antidepressants: If these medicines and Bendroflumethiazide Evolan are taken simultaneously postural hypotension may occur (drop in blood pressure on standing up);
- Carbamazepine and amphotericin: If you take these medicines and Bendroflumethiazide Evolan, an increased risk in lower of sodium levels can occur;
- Calcium salts or vitamin D preparations: The risk of hypercalcaemia (abnormally high levels of potassium) increases if you take these products and Bendroflumethiazide Evolan;
- Cisplatin: There may be an increased risk of nephrotoxicity (kidney impairment) and ototoxicity (ear problems) if you take this medicine and simultaneously take Bendroflumethiazide Evolan;
- Disopyramide, amiodarone, flecainide and quinidine: The cardiac toxicity of these medicines is increased if hypokalaemia occurs (low blood levels of potassium);
- Lidocaine and mexiletine: Their action is blocked if there is a reduction of potassium levels
- Aminoglutethimide: There is an increased risk of hyponatraemia (low blood levels of sodium);
- Toremifene and reboxetine: Can cause an increased risk of hypercalcaemia (high blood levels of potassium);
- Colestipol and colestyramine: They may reduce the absorption of thiazide. For this reason, they should be given two hours prior to or two hours after the ingestion of Bendroflumethiazide Evolan;
- Calcium-channel blockers and moxisylyte: May cause an enhanced hypotensive effect (drop in blood pressure);
- Oestrogens and combined oral contraceptives: May antagonise the diuretic effect of thiazides, such as Bendroflumethiazide Evolan;
- Pimozide, thioridazine or terfenadine: If there is hypokalaemia (low blood levels of potassium), the risk of ventricular arrhythmias can increase.

Bendroflumethiazide Evolan with food, drink and alcohol:
Do not drink alcohol while taking Bendroflumethiazide , because it can cause postural hypotension (drop in blood pressure on standing up).

Pregnancy, breast-feeding and fertility:
Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy:
Diuretics should be avoided for the management of oedema or hypertension in pregnancy.
They may cause a decrease in placental perfusion, foetal electrolyte disturbances and other reactions.
Cases of neonatal thrombocytopenia (reduction of the number platelets in the blood), or foetal or neonatal jaundice (yellow color on skin and mucosas) have been reported with maternal thiazide therapy. Bendroflumethiazide is not recommended during the first trimester of pregnancy.

Breast-feeding:
As diuretics pass into breast milk and Bendroflumethiazide Evolan can suppress lactation, its use should be avoided in women who wish to breastfeed.

Driving and using machines:
No studies on the effects on the ability to drive and use machines have been performed.

Bendroflumethiazide Evolan contains lactose:
If you have been told you have intolerance to some sugars, speak with your doctor before taking this medicine.

3. HOW TO TAKE BENDROFLUMETHIAZIDE EVOLAN

Always take Bendroflumetiazide Evolan tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

Adults:
In case of oedema, the initial dose is 5-10 mg in the morning, daily or on alternate days. The maintenance dose is 5-10 mg one to three times weekly.
In case of hypertension, the usual dose is 2.5 mg taken in the morning. Higher doses are rarely necessary.

Paediatric patient (children):
Dosage in children may be up to 400 mcg/kg bodyweight initially, reducing to 50-100 mcg/kg bodyweight daily for maintenance.

Elderly patients:
The dosage of thiazide diuretics, such as Bendroflumethiazide Evolan, may need to be reduced in the elderly patients, particularly when renal function is impaired, due to the possibility of electrolyte imbalance.

If you have kidney or liver problems, you should tell your doctor.

If you take more Bendroflumethiazide Evolan than you should:
Inform your doctor immediatly if you take more tablets of Bendroflumethiazide Evolan than you should or contact the nearest hospital for assistance.

Symtptoms: anorexia, nausea, vomiting, diarrhoea, dieresis (excessive urine excretion), dehydration, hypotension (reduction of arterial pressure), dizziness, weakness, muscle cramps, paraesthesia (cutaneous sensations, as for example, cold, hot, tingling, pressure, e.g., spontaneously felt in the absence of stimulation), tetany (involuntary muscular contraction), gastrointestinal bleeding, hyponatraemia (low blood levels of sodium), hypo- or hyperglycaemia, hypokalaemia (low blood levels of potassium) and metabolic alkalosis (high blood levels of biocarbonate).

If you forget to take Bendroflumethiazide Evolan:
Do not take a double dose to make up for a forgotten dose.

If you stop taking Bendroflumethiazide Evolan:
You should take into consideration that hypotension (drop in blood pressure on standing up) can usually occur during three to four days after last intake.

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 Evolan can cause side effects, although not everybody gets them.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please contact your doctor or pharmacist.

All thiazide diuretics may produce a degree of electrolytes imbalance, e.g. hypokalaemia.

Thiazide diuretics may raise serum uric acid levels with consequent exacerbation of gout in susceptible patients.

Thiazide diuretics sometimes lower carbohydrate tolerance and the insulin dosage of the diabetic patients may require adjustment. Care is required when bendroflumethiazide is administered to those with a known predisposition to diabetes.

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) has been reported after the use of thiazide and thiazide-like diuretics.

Impotence has been reported which is reversible on withdrawal of treatment.

The following undesirable effects, which are listed in system order class, have previously been associated with bendroflumethaizide:

Specific frequencies for the occurrence of these effects are not available.

Blood and lymphatic system disorders:
Agranulocytosis (low levels of blood cells, specifically white cells named granulocytes), aplastic anaemia (low blood levels of red cells due to a change in bone marrow), neutropenia, thrombocytopenia (neonatal thrombocytosis reported when given in late pregnancy) (low blood levels of platelets in the blood).

Immune system disorders:
Hypersensitivity reactions.

Metabolism and nutrition disorders:
Gout, hyperglycaemia (high blood levels of sugar).

Cardiac and vascular disorders:
Postural hypotension.

Respiratory, thoracic and mediastinal disorders:
Pneumonitis, pulmonary oedema.

Gastrointestinal effects:

Mild gastro-intestinal effects have been reported, pancreatitis (pancreas´s inflammation).

Hepato-biliary disorders:
Intrahepatic cholestasis (liver blockage or impairment).

Skin and subcutaneous tissue disorders:
Rash, photosensitivity, severe skin reactions also reported.

Reproductive system and breast disorders:
Impotence.

Investigations:
Hypokalaema (low blood levels of potassium levels), hypomagnesaemia (low blood levels of magnesium levels), hyponatraemia (low blood levels of sodium), hypercalcaemia (high blood levels of calcium), hypochloraemic (low blood levels of chlorides) alkalosis (low levels of acid levels in body fluids), hyperuricaemia (high blood levels of uric acid), altered plasma lipid (fat) concentrations.

5. HOW TO STORE BENDROFLUMETHIAZIDE EVOLAN

Keep this medicine out of the sight and reach of children.
Keep inside original pack and at temperatures lower than 25ºC.

Do not use Bendroflumethiazide Evolan 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 use Bendroflumethiazide Evolan if you notice visible signs of deterioration.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Bendroflumethiazide Evolan contains:
The active substance is bendroflumethiazide.
The other ingredients are:
Lactose
Pre-jellified maize starch
Purified talc
Stearic acid.

What Bendroflumethiazide Evolan looks like and contents of the pack:
2,5 mg tablets are white or almost white, circular and biconvex.
5 mg tablets are white or almost white, circular with flat beveled-edge, with “5” embossed on one side of the tablet.
Packs containing 14, 28 or 56 tablets in PVDC/PVC/Alu blister and 100 or 500 tablets in HDPE-bottles.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:
Evolan Pharma AB
Box 120
18212 Danderyd
Sverige

Manufacturer:
Sofarimex – Indústria Química e Farmacêutica, S.A.
Alto do Colaride
2735-213 Cacém
Portugal

or

Evolan Pharma AB
Svärdvägen 19 182 33 Danderyd

Further information or queries regarding the use of this product please contact the Marketing Authorization Holder:
Evolan Pharma AB
Box 120
18212 Danderyd
Sverige

This leaflet was last approved in

2021-07-07