

# Aprinox<sup>®</sup> 2.5 mg and 5 mg Tablets

Bendroflumethiazide



## Read all of this leaflet carefully before you start taking this medicine.

- Please 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes severe, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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### 1. WHAT APRINOX 2.5 MG AND 5 MG TABLETS ARE AND WHAT THEY ARE USED FOR

The active ingredient in this medicine is bendroflumethiazide.

Aprinox belongs to a class of medicines known as diuretics. Diuretic medicines are those that promote the excretion of urine. Aprinox Tablets are used to treat hypertension (high blood pressure) and oedema (fluid retention). They are also used to stop the production of breast milk.

### 2. BEFORE YOU TAKE APRINOX 2.5 MG AND 5 MG TABLETS Do not take this medicine if:

- you ever had an allergic reaction to Aprinox 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);
- 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.

### Take special care and tell your doctor or pharmacist if:

- you suffer from gout;
- you are diabetic;
- 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.

Tell your doctor before taking this medicine if you have been told that you have an **intolerance to some sugars**. This is because Aprinox 2.5 mg and 5 mg Tablets contains a small amount of lactose, a type of sugar.

### Taking other medicines

Tell your doctor if you are taking any other medicines, especially the following:

- 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 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, 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 Moxislyte, 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 monoamine oxidase inhibitors);
- medicines used to treat a condition known as multiple sclerosis or spinal injuries (eg. 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 Aprinox 2.5 mg and 5 mg Tablets 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 Aprinox Tablets.
- Colestipol and colestyramine may reduce the absorption of thiazide diuretics and should therefore be given 2 hours prior to, or after the ingestion of Aprinox.
- 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 and breast-feeding

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

### Driving and using machines

Aprinox 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.

### 3. HOW TO TAKE APRINOX 2.5 MG AND 5 MG TABLETS

Always take your medicine exactly as your doctor has told you. You should 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.

**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 5 to 10 mg one to three times weekly.

**Suppression of breast milk:** The usual dose is 5 mg taken in the morning and 5 mg taken at midday. Treatment usually lasts for approximately five days.

**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.

**Elderly:** The dose of Aprinox 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 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 your medicine

If you forget to take a dose, just take the next dose at the usual time, DO NOT take a double dose.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines Aprinox 2.5 mg and 5 mg Tablets can cause unwanted side effects in some people, although it is generally well tolerated. 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.

### 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, Aprinox 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 Aprinox 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 Aprinox at the same time.

If any of the side effects become severe, or if you notice any side effects not listed in this leaflet, please **tell your doctor or pharmacist immediately.**

### 5. HOW TO STORE APRINOX 2.5 MG AND 5 MG TABLETS

Do not store above 25° C. Keep the container tightly closed and store in the original container. Do not use after the expiry date that is stated on the carton.

### KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN

Return any unused medicine to your pharmacist.

### 6. FURTHER INFORMATION

#### What Aprinox 2.5 mg and 5 mg Tablets contain

Each tablet contains 2.5 mg or 5 mg of the active substance bendroflumethiazide.

The other ingredients are: lactose, maize starch, stearic acid and French chalk.

#### What Aprinox 2.5 mg and 5 mg Tablets look like and the contents of the pack:

The tablets are round and white and are available in two different strengths containing either 2.5 mg or 5 mg.

Aprinox 2.5 mg and 5 mg Tablets are available in blister packs containing 28 tablets and bulk packs of 100 or 500 tablets.

#### Marketing Authorisation Holder and Manufacturer:

Waymade Plc trading as Sovereign Medical, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR.

This leaflet does not contain all the available information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

The information in this leaflet applies only to Aprinox 2.5 mg and 5 mg Tablets

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