Consumer Medicine Information

Arrow - Bendrofluazide

Bendroflumethiazide 2.5 mg and 5 mg tablets

What is in this leaflet

Please read this leaflet carefully before you start taking ARROW-BENDROFLUAZIDE.

This leaflet answers some common questions about ARROW-BENDROFLUAZIDE. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ARROW-BENDROFLUAZIDE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What ARROW - BENDROFLUAZIDE is used for

ARROW-BENDROFLUAZIDE contains the active ingredient bendroflumethiazide, also known as bendrofluazide.

ARROW-BENDROFLUAZIDE is a fluid tablet or diuretic. It helps reduce the amount of excess fluid in the body by increasing the amount of urine produced. It is used to treat swelling of the ankles, feet or legs, which is called oedema. This can occur in some heart, liver or kidney conditions.

ARROW-BENDROFLUAZIDE is also used to treat high blood pressure either alone or in combination with other medicines.

Your doctor may have prescribed ARROW-BENDROFLUAZIDE for another reason.

Ask your doctor if you have any questions about why ARROW-BENDROFLUAZIDE has been prescribed for you.

ARROW-BENDROFLUAZIDE is available only with a doctor's prescription.

Before you take ARROW-BENDROFLUAZIDE

When you must not take it

Do not take ARROW-BENDROFLUAZIDE if you have had an allergic reaction to bendroflumethiazide or any of the ingredients in ARROW-BENDROFLUAZIDE listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- · shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- lumpy skin rash ("hives"), hayfever or fainting.

Do not take ARROW-BENDROFLUAZIDE if you have an allergy or have ever had an allergic reaction to medicines which contain sulphur such as antibiotic medicines called sulphonamides.

Do not take ARROW-BENDROFLUAZIDE if you have any of the following medical conditions:

- Addison's disease (a condition affecting the adrenal glands)
- diabetic ketoacidosis (a complication of diabetes)
- severe liver or kidney failure
- high calcium levels in your blood (hypercalcaemia)

Do not take ARROW-BENDROFLUAZIDE if you are taking lithium carbonate.

Before you start taking ARROW-BENDROFLUAZIDE

Tell your doctor if you are pregnant or plan to become pregnant.

ARROW-BENDROFLUAZIDE may be harmful to both mother and unborn baby when taken by a pregnant woman. You should avoid becoming pregnant while taking ARROW-BENDROFLUAZIDE. If you are already pregnant, your doctor will weigh up the expected benefits of ARROW-BENDROFLUAZIDE to you and your unborn baby against its possible risks.

Tell your doctor if you are breastfeeding or planning to breastfeed.

The active ingredient in ARROW-BENDROFLUAZIDE, bendroflumethiazide, passes into breast milk and therefore breastfeeding should be avoided.

Tell your doctor if you have or have had any medical conditions, especially the following:

- diabetes
- gout
- liver or kidney problems
- · high cholesterol in the blood
- systemic lupus erythematosus (a rare autoimmune disease)
- heart disease
- prostate problems

Tell your doctor if you have allergies to any other medicines, foods, dyes or preservatives.

If you have not told your doctor about any of the above, tell them before you start taking ARROW-BENDROFLUAZIDE.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

If you are taking any of the following types of medicines, please let your doctor know before taking ARROW-BENDROFLUAZIDE:

- MAOIs, used to treat depression
- lithium carbonate, a medicine used to treat mood swings and some types of depression
- non-steriodal anti-inflammatory medicines (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- · medicines used to treat high blood pressure and some other heart conditions
- · digoxin, a medicine used to treat heart failure
- · narcotics/strong pain killers

- barbiturates, medicines used to treat epilepsy, to produce calmness or to help you sleep
- sulphonylurea drugs taken for diabetes
- · medicines used to treat gout such as allopurinol
- steroid medicines such as cortisone, prednisone and dexamethasone
- tablets, preparations or supplements which contain potassium
- carbenoxolone, a medicine used to treat mouth ulcers
- alcohol

If you need to have an operation while taking ARROW-BENDROFLUAZIDE, please discuss this with your doctor. The side effects of some anaesthetic drugs can be increased in people taking ARROW-BENDROFLUAZIDE.

Your doctor or pharmacist will be able to tell you more about what to do when taking ARROW-BENDROFLUAZIDE with other medicines.

Taking ARROW-BENDROFLUAZIDE

How much to take

Take ARROW-BENDROFLUAZIDE exactly as your doctor has prescribed.

Your doctor will tell you how many ARROW-BENDROFLUAZIDE tablets to take each day.

Never take more tablets than your doctor has prescribed.

Your doctor may vary your dose depending on how you respond to ARROW-BENDROFLUAZIDE.

In adults, the usual dose is 2.5mg to 10mg daily, depending on the condition being treated. Some people may need to take ARROW-BENDROFLUAZIDE every day, but other people may be able to take it every second or third day.

For children up to 12 years of age, the usual dose is $50\mu g$ to $100\mu g$ per kilogram of body weight daily.

Elderly people are sensitive to the effects of ARROW-BENDROFLUAZIDE on their blood pressure and potassium levels therefore a reduced dose and potassium supplement is needed.

How to take it

Swallow tablets whole with a glass of water early in the day.

If you forget to take it

Do not take an extra dose. Wait until the next dose and take your normal dose then.

Do not try to make up for the dose that you missed by taking more than one dose at a time.

If you are not sure what to do, ask your doctor or pharmacist.

In case of an overdose

Immediately telephone your doctor, or the National Poisons Information Centre (0800 POISON or 0800 764 766), or go to the Accident and Emergency department at your nearest hospital, if you think that you or anyone else may have taken too many ARROW-BENDROFLUAZIDE.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep the telephone numbers for these places handy.

An overdose of ARROW-BENDROFLUAZIDE can cause drowsiness, lethargy, loss of consciousness, abnormal breathing and poor heart function.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking ARROW-BENDROFLUAZIDE

Things you must do

Tell all doctors and pharmacists involved in your health care that you are taking ARROW-BENDROFLUAZIDE.

Tell your doctor if you become pregnant while taking ARROW-BENDROFLUAZIDE.

Tell your doctor if, for any reason, you have not taken ARROW-BENDROFLUAZIDE exactly as prescribed. Otherwise, your doctor may think it is not working for you and change your ARROW-BENDROFLUAZIDE dose unnecessarily.

Tell your doctor if you feel that ARROW-BENDROFLUAZIDE is not helping your condition.

Tell your doctor if you are vomiting, have diarrhoea, or you suffer from a chronic illness, because you may need a potassium supplement while you are taking ARROW-BENDROFLUAZIDE.

Things you must not do

Do not stop taking ARROW-BENDROFLUAZIDE or change the dose without first checking with your doctor, or your symptoms could return.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give ARROW-BENDROFLUAZIDE to anyone else even if they have the same condition as you.

Do not take any other medicines whether they require a prescription or not without first asking your doctor or a pharmacist.

Do not drink large amounts of alcohol. Use of ARROW-BENDROFLUAZIDE with alcohol will increase your chances of getting dehydrated and a hangover.

Do not drive or operate machinery until you know how your ARROW-BENDROFLUAZIDE dose is affecting you.

Side-Effects

All medicines can have unwanted side effects. Sometimes they may be serious, but often they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Be sure that your doctor or pharmacist knows as soon as possible if you do not feel well while you are taking ARROW-BENDROFLUAZIDE.

If you think you are having an allergic (hypersensitivity) reaction to ARROW-BENDROFLUAZIDE, tell your doctor immediately. Symptoms include:

- Severe skin rash, itching or hives
- · Swelling of the face, lips, mouth or throat
- Difficulty breathing or swallowing
- Fever
- Low blood pressure (feeling faint or dizzy).

Tell your doctor if you notice any of the following:

- very dry mouth or unusual thirst
- · passing urine more often than normal
- weakness
- dizziness
- muscle cramps
- · vomiting or nausea
- · loss of appetite
- stomach pain
- · diarrhoea or constipation
- · rashes or small red spots on your skin
- · attacks of gout
- postural hypotension (feeling dizzy and faint when you stand up)
- impotence

ARROW-BENDROFLUAZIDE may also affect the composition of your blood. Your doctor may do regular blood tests to check for these side effects.

Most of the above side effects are caused by excessive loss of potassium in urine when you take ARROW-BENDROFLUAZIDE. Your doctor may prescribe a potassium supplement and/or reduce your dose of ARROW-BENDROFLUAZIDE to prevent these side effects.

You may pass very large amounts of urine in the first few days after starting ARROW-BENDROFLUAZIDE, but the amounts become smaller as you continue taking this medicine.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you do not understand anything on this list.

After taking ARROW-BENDROFLUAZIDE

Storage

Keep ARROW-BENDROFLUAZIDE where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in the container in a cool dry place where the temperature stays below 25°C.

Do not store ARROW-BENDROFLUAZIDE or any other medicines in the bathroom or near a sink. Do not leave the tablets in the car or on window sills.

Heat, light and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking ARROW-BENDROFLUAZIDE, or your tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product Description

What ARROW-BENDROFLUAZIDE looks like

ARROW-BENDROFLUAZIDE is available in 2.5mg and 5mg tablets:

ARROW-BENDROFLUAZIDE 2.5 are white to almost white, circular, biconvex, uncoated tablets.

ARROW-BENDROFLUAZIDE 5 are white to almost white, circular, flat, bevelled edged uncoated tablets with '5' embossed on one side.

Ingredients

The active ingredient in ARROW-BENDROFLUAZIDE tablets is bendroflumethiazide, also known as bendrofluazide:

ARROW-BENDROFLUAZIDE 2.5 tablet contain 2.5 mg of bendroflumethiazide. ARROW-BENDROFLUAZIDE 5 tablet contains 5 mg of bendroflumethiazide.

The tablets also contain:

- Lactose
- Pregelatinised starch
- Purified talc
- Stearic acid

The tablets do not contain gluten, sucrose, tartrazine or any azo dyes.

Supplier

ARROW-BENDROFLUAZIDE is distributed in New Zealand by:

Teva Pharma (New Zealand) Limited PO Box 128 244 Remuera Auckland 1541

Telephone: 0800 800 097

Date of preparation

4 May 2017