

CONSUMER MEDICINE INFORMATION

Arrow – Losartan Potassium & Hydrochlorothiazide

Losartan potassium 50 mg and hydrochlorothiazide 12.5 mg tablets

What is in this leaflet

Please read this leaflet carefully before you start using ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE.

This leaflet answers some common questions about ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you using ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE against the benefits they expect it will have for you.

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

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

What ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE is used for

ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE is a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide). Losartan and hydrochlorothiazide work together to lower high blood pressure. Losartan lowers blood pressure by specifically blocking a substance called angiotensin II. Angiotensin II normally tightens your blood vessels. The losartan ingredient in ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE allows them to relax. Hydrochlorothiazide works by making your kidneys pass more water and salt.

ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE lowers high blood pressure, which doctors call hypertension. It may be used alone or in combination with other medicines. In patients with high blood pressure and a thickening of the left ventricle, losartan, often in combination with hydrochlorothiazide, reduces the risk of stroke and heart attack and helps patients live longer.

Everyone has blood pressure. This pressure helps get your blood all around your body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems. You may feel fine and have no symptoms, but eventually hypertension can cause stroke, heart disease and kidney failure. Over time, high blood pressure causes the heart to work harder, which can lead to a thickening of the left ventricle. A thickening of the left ventricle of the heart is associated with an increased chance of experiencing a stroke.

Your doctor may have prescribed ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE for another reason. Ask your doctor if you have any questions

about why ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE has been prescribed for you.

ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE is not addictive.

This medicine is available only with a doctor's prescription.

Before you take ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE

When you must not use it

Do not use ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE if:

- you have an allergy to losartan, hydrochlorothiazide or any of the ingredients listed at the end of this leaflet.
- you have an allergy to any sulphonamide or sulphur medicines. One of the ingredients in ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE, hydrochlorothiazide, is a sulphur containing medicine (a sulphonamide). Therefore, if you are allergic to sulphur medicines, such as some antibiotics, you are likely to be allergic to ARROW LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE. Check with your doctor or pharmacist if you are not sure whether you are allergic to sulphur medicines. Symptoms of an allergic reaction may include skin rash, hives, fever, swelling of the face, lips, mouth, throat or tongue which may cause difficulty breathing or swallowing.
- you are pregnant or breast-feeding. Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.
- you are not passing urine.
- you have diabetes and are taking a medicine called aliskiren to reduce blood pressure.
- the packaging is torn or shows signs of tampering.
- the expiry date (EXP) printed on the pack has passed. If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE, talk to your doctor.

Do not give ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE to a child. The safety and effectiveness of ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE in children have not been established.

Before you start to take it

Tell your doctor if:

- you intend to become pregnant or plan to breast-feed. ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE is not recommended for use during pregnancy or while breast-feeding.
- you have any medical conditions, especially the following: liver disease, kidney disease, diabetes, gout, lupus erythematosus (known as SLE), a disease affecting the skin, joints and kidneys
- high cholesterol or triglyceride levels
- you have recently had excessive vomiting or diarrhoea
- if you have any allergies to any other medicines or any other substances, such as foods preservatives or dyes

If you have not told your doctor about any of the above, tell them before you take ARROW – LOSARTAN & HYDROCHLOROTHIAZIDE.

Taking other medicines

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

Some medicines and ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE may interfere with each other. These include:

- other fluid tablets (diuretic), also called water tablets, including potassium-sparing diuretics
- potassium tablets
- potassium-containing salt substitutes
- other medicines used to treat high blood pressure
- digoxin, used to treat heart failure
- lithium, used to treat severe mood swings and some types of depression
- steroid medicines such as cortisone, prednisone and glycyrrhizin found in liquorice root
- insulin and tablets used to treat diabetes
- barbiturates, used to treat epilepsy, such as phenobarbitone
- strong pain killers such as codeine, morphine, dextropropoxyphene
- non-steroidal anti-inflammatory medicines (NSAIDs) including cyclooxygenase- 2 inhibitors (COX-2) used to treat inflammation, pain, arthritis
- cholestyramine and colestipol, used to treat high cholesterol
- medicines used to relax muscles before and during surgery
- medicines used in emergency situations such as adrenaline
- alcohol

These medicines may be affected by ARROW – LOSARTAN & HYDROCHLOROTHIAZIDE, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking ARROW – LOSARTAN & HYDROCHLOROTHIAZIDE.

How to take ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE

How much to take

Take ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE only when prescribed by your doctor. Your doctor will tell you how many tablets you need to take each day. This depends on your condition and whether you are taking other medicines.

For most patients, the usual dose is one tablet of ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE once a day.

Depending on your condition, the dose may need to be increased to two tablets of ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE once a day.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

When to take it

Take your ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE at about the same time each day. Taking your tablet(s) at the same time each day will have the best effect. It will also help you remember when to take the tablet(s).

Swallow ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE with a glass of water. It does not matter whether you take ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE before or after food.

How long to take it

ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE helps control your high blood pressure but does not cure it. Therefore ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE must be taken every day. Continue taking ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE for as long as your doctor prescribes.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablet(s) as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too many tablets, you will probably feel light-headed or dizzy, or you may faint.

You may also become very thirsty, confused, have a change in the amount of urine passed or have a fast or irregular heart beat.

While you are taking ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE

Things you must do

If you become pregnant while taking ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE, tell your doctor immediately.

Have your blood pressure checked when your doctor says, to make sure ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE is working.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

You may feel light-headed or dizzy when you begin to take ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE. This is because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem gets worse or continues, talk to your doctor.

If you have excessive vomiting and/or diarrhoea while taking ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE, or you have any of the following symptoms, tell your doctor:

- dry mouth, thirst
- weakness, tiredness, drowsiness
- muscle pains or cramps
- fast heart beat
- passing less urine than normal

You may be dehydrated because you are losing too much water and your blood pressure may become too low.

Make sure you drink enough water during exercise and hot weather when you are taking ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE, especially if you sweat a lot. If you do not drink enough water while taking ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE, you may faint or feel light-headed or sick. This is because your body doesn't have enough fluid and your blood pressure is low. If you continue to feel unwell, tell your doctor.

If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE.

Continue taking potassium tablets if your doctor has prescribed these for you. ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE contains a very small amount of potassium, but this does not replace any potassium tablets that you may be taking.

Things you must not do

Do not give ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE to anyone else, even if they have the same condition as you.

Things to be careful of

Make sure you know how you react to ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE before you drive a car, operate machinery, or do anything else that could be dangerous.

If you drink alcohol, or take strong pain killers or barbiturates, the effects may be worse.

Things that would be helpful for your blood pressure or heart failure

Some self help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- Alcohol - your doctor may advise you to limit your alcohol intake.
- Diet - eat a healthy diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar.
- Exercise - regular exercise helps to reduce blood pressure. Try regular walking, swimming, cycling or games such as tennis and golf. Before starting any exercise, ask your doctor about the best kind of programme for you.
- Salt - your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake you should avoid using salt in cooking or at the table.
- Smoking - your doctor may advise you to stop smoking or at least cut down.
- Weight - your doctor may suggest losing some weight to help lower your blood pressure and help lessen the amount of work your heart has to do. Some people may need a dietician's help to lose weight.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE.

ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE helps most people with high blood pressure, but it may have unwanted adverse effects in a few people. All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

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

Tell your doctor if you notice any of the following and they worry you:

- nausea
- vomiting
- cramping
- constipation
- restlessness
- headache
- weakness
- dizziness
- dizziness/light-headedness; due to a sudden drop in blood pressure when standing up quickly
- fatigue
- taste alteration
- transient blurred vision
- cough
- rash
- dermatitis
- increased sensitivity of the skin to sun

These are usually mild adverse effects of ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE but may be serious.

Tell your doctor immediately if you notice any of the following:

- diarrhoea
- yellowing of the skin and/or eyes, also called jaundice

These may be serious adverse effects. You may need urgent medical attention.

Serious adverse effects are rare.

Tell your doctor immediately or go to accident and emergency at your nearest hospital if you notice any of the following:

- swelling of the face, lips, mouth, throat or tongue which may cause difficulty swallowing or breathing
- shortness of breath
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettlerash
- severe skin reaction which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell.

These are serious adverse effects. You may need urgent medical attention or hospitalisation.

All of these adverse effects are rare.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After taking ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE

Storage

Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack, they may not keep well.

Keep ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE 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 ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE in a cool, dry place where the temperature stays below 25°C. Do not store ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE or 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 – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE, 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 – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE like

ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE tablets are yellow coloured, oval shaped, biconvex, film-coated tablets.

Ingredients

The active ingredients in ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE are losartan potassium and hydrochlorothiazide. Each tablet contains 50 mg of losartan potassium and 12.5 mg of hydrochlorothiazide.

The tablets also contain:

- lactose monohydrate
- microcrystalline cellulose
- pregelatinised starch
- maize starch
- colloidal anhydrous silica
- magnesium stearate
- hydroxyl propyl methyl cellulose
- titanium dioxide
- purified talc

- macrogol 6000
- quinoline yellow lake
- purified water

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

Supplier

ARROW – LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE is distributed in New Zealand by:

Teva Pharma (New Zealand) Limited
PO Box 128 244
Remuera
Auckland 1541
Telephone: 0800 800 097

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