

HYZAAR[®]

losartan potassium and hydrochlorothiazide
50/12.5 mg tablet

What is in this leaflet

This leaflet answers some common questions about HYZAAR. It does not contain all the available information. It does not take the place of talking to your doctor and pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking HYZAAR 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 HYZAAR is used for

HYZAAR 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 or 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 HYZAAR for another reason. Ask your doctor if you have any questions about why HYZAAR has been prescribed for you.

HYZAAR is not addictive.

How does HYZAAR work

HYZAAR 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 HYZAAR allows them to relax. Hydrochlorothiazide works by making your kidneys pass more water and salt.

Before you take HYZAAR

When you must not take it

Do not take HYZAAR if:

- you have an allergy to HYZAAR, COZAAR[®], or any of the ingredients listed at the end of this leaflet
- you have an allergy to any sulfonamide or sulfur medicines.
One of the active ingredients in HYZAAR, hydrochlorothiazide, is a sulfur-containing medicine (a sulfonamide). Therefore, if you are allergic to sulfur medicines, such as some antibiotics, you are likely to be allergic to HYZAAR.
Check with your doctor or pharmacist if you are not sure whether you are allergic to sulfur 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
- 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 HYZAAR, talk to your doctor.

Do not give HYZAAR to a child. The safety and effectiveness of HYZAAR 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.
HYZAAR 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 HYZAAR.

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 HYZAAR 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 HYZAAR, 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 HYZAAR.

How to take HYZAAR

How much to take

Take HYZAAR 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 HYZAAR 50/12.5 once a day. Depending on your condition, the dose may need to be increased to two tablets of HYZAAR 50/12.5 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 HYZAAR 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 tablets.

Swallow HYZAAR with a glass of water.

It does not matter whether you take HYZAAR before or after food.

How long to take it

HYZAAR helps control your high blood pressure but does not cure it. Therefore HYZAAR must be taken every day. Continue taking HYZAAR 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 HYZAAR. 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 using HYZAAR

Things you must do

If you become pregnant while taking HYZAAR, tell your doctor immediately.

Have your blood pressure checked when your doctor says, to make sure HYZAAR is working.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking HYZAAR.

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 HYZAAR. 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 HYZAAR, 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 HYZAAR, especially if you sweat a lot. If you do not drink enough water while taking HYZAAR, 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 HYZAAR.

Continue taking potassium tablets if your doctor has prescribed these for you. HYZAAR

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 HYZAAR to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how HYZAAR affects you. Make sure you know how you react to HYZAAR 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

Some self help measures suggested below may help your blood pressure. 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. Some people may need a dietician's help to lose weight.

Adverse Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking HYZAAR.

HYZAAR 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, but 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 HYZAAR, 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 nettle rash
- 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. If you have them, you may have had a serious allergic reaction to HYZAAR. You may need urgent medical attention or hospitalisation. 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 using HYZAAR

Storage

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

Keep HYZAAR in a cool dry place where the temperature stays below 30°C. Do not store it or any other medicines in the bathroom or near a sink. Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

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

Product description

What it looks like

HYZAAR 50/12.5 mg - yellow, oval-shaped tablet with 717 marked on one side and plain on the other.

A pack contains 30 tablets.

Ingredients

Active ingredient:

HYZAAR 50/12.5 mg - 50 mg losartan potassium and 12.5 mg hydrochlorothiazide per tablet.

Inactive ingredients:

- lactose
- microcrystalline cellulose
- hydroxypropylcellulose
- hypromellose
- pregelatinised maize starch
- magnesium stearate
- carnauba wax
- titanium dioxide
- quinolone yellow FCF CI 47005 or yellow coating concentrate

HYZAAR does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

HYZAAR is supplied in New Zealand by:

Merck Sharp & Dohme (New Zealand) Limited
P O Box 99851
Newmarket
Auckland
NEW ZEALAND
Tel: 0800 500 673

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