

HYZAAR[®]/FORTZAAR[®]

Losartan Potassium/Hydrochlorothiazide (50mg/12.5mg, 100mg/12.5mg, 100mg/25mg)

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Please read this leaflet carefully before you start to take your medicine, even if you have just refilled your prescription. Some of the information in the previous leaflet may have changed.

Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

What HYZAAR/FORTZAAR is used for

HYZAAR/FORTZAAR is a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide). Losartan and hydrochlorothiazide work together to lower high blood pressure. If you have high blood pressure and a thickening of the left ventricle, the heart's main pumping chamber, your doctor has prescribed HYZAAR/FORTZAAR to help lower the risk of cardiovascular events, such as stroke.

How HYZAAR/FORTZAAR works

The losartan ingredient of HYZAAR/FORTZAAR lowers blood pressure by specifically blocking a substance called angiotensin II. Angiotensin II normally tightens your blood vessels. The losartan ingredient of HYZAAR/FORTZAAR allows them to relax. The hydrochlorothiazide ingredient of HYZAAR/FORTZAAR works by making your kidneys pass more water and salt. Together, losartan and hydrochlorothiazide lower high blood pressure. Although your doctor will be able to tell you that the medicine is working by measuring your blood pressure, you probably will feel no different while you are taking HYZAAR/FORTZAAR.

Why has my doctor prescribed HYZAAR/FORTZAAR?

Your doctor has prescribed HYZAAR/FORTZAAR because you have a condition known as hypertension or high blood pressure. 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 (see **“Before you take HYZAAR/FORTZAAR”**, **“Use in Black patients with high blood pressure and a thickening of the left ventricle”**).

What is blood pressure?

The pressure caused by your heart pumping blood to all parts of your body is called blood pressure. Without blood pressure there would be no circulation of blood in your body. Normal blood pressure is part of good health. Your blood pressure changes during the day

depending on activity, stress and excitement.

Your blood pressure is made up of two numbers, for instance 120/80. The top number measures the force while your heart pumps. The bottom number measures the force at rest, between heartbeats.

What is high blood pressure (or hypertension)?

You have high blood pressure or hypertension if your blood pressure stays high even when you are calm and relaxed. High blood pressure develops when blood vessels tighten, making it harder for blood to pass.

How do I know if I have high blood pressure?

There are usually no symptoms of high blood pressure. The only way of knowing that you have hypertension is to know your blood pressure. For that reason, you should have your blood pressure checked on a regular basis.

Why should high blood pressure be treated?

High blood pressure if left untreated can damage vital organs like the heart and the kidneys. You may feel fine and have no symptoms, but eventually hypertension can cause strokes, heart attacks, heart failure, kidney failure or blindness.

How should high blood pressure be treated?

Once high blood pressure is diagnosed, some treatments other than drugs may be recommended. Your doctor may recommend some changes in lifestyle. Your doctor may decide that you also need medicine to control your blood pressure. High blood pressure can be treated and controlled by taking

medicines such as HYZAAR/FORTZAAR.

Your doctor can tell you what your individual blood pressure target should be. Keep this number in mind and follow your doctor's advice on how to reach this target.

What causes a thickening of the left chamber of the heart?

High blood pressure causes the heart to work harder. Over time, this may cause the heart to thicken.

Why should patients with a thickening of the left ventricle of the heart be treated?

A thickening of the left ventricle of the heart is associated with an increased chance of experiencing a stroke. In patients with high blood pressure and a thickening of the left chamber of the heart, losartan has been shown to reduce the risk of cardiovascular events, such as stroke.

Before you take HYZAAR/FORTZAAR

When you must not take it

Do not take HYZAAR/FORTZAAR if you:

- are allergic to any of its ingredients (see **What HYZAAR/FORTZAAR is used for** section)
- are allergic to any sulfonamide-derived drugs (ask your doctor if you are not sure what sulfonamide-derived drugs are)
- are not passing urine
- have diabetes and are taking a medicine called aliskiren to reduce blood pressure

If you are not sure whether you should start taking HYZAAR/FORTZAAR, contact your doctor.

Before you start to take it

Tell your doctor or pharmacist about any medical problems you have or have had, and about any allergies. Tell your doctor if you

have recently suffered from excessive vomiting or diarrhea.

It is particularly important to tell your doctor if you have liver or kidney disease, gout, diabetes, lupus erythematosus, or if you are being treated with other diuretics (water tablets). In these cases, your doctor may need to adjust the dose of your medications.

Before surgery and anesthesia (even at the dentist's office), tell the doctor or dentist that you are taking HYZAAR/FORTZAAR, as there may be a sudden fall in blood pressure associated with the anesthesia.

Taking other medicines

In general, HYZAAR/FORTZAAR can be taken with other drugs. You should, however, tell your doctor about all drugs that you are taking or plan to take, including those obtained without a prescription. It is especially important for your doctor to know if you are taking potassium supplements, potassium-sparing agents or salt substitutes containing potassium, other drugs to reduce blood pressure, other diuretics (water tablets), resins which reduce high cholesterol, medications to treat diabetes including insulin, muscle relaxants, pressor amines such as adrenaline, steroids, certain pain and arthritis medicines, or lithium (a drug used to treat a certain kind of depression). Sedatives, tranquilizers, narcotics, alcohol and analgesics may increase the blood pressure-lowering effect of HYZAAR/FORTZAAR, so tell your doctor if you take any of these drugs.

How to take HYZAAR/FORTZAAR

How much to take

High Blood Pressure

The usual dose for most patients with high blood pressure is 1 tablet

of HYZAAR 50/12.5mg per day to control blood pressure over the 24-hour period.

Patients with high blood pressure and a thickening of the left ventricle

The usual starting dose is 50 mg of losartan once daily. If goal blood pressure is not reached with losartan 50 mg, your doctor may prescribe a combination of losartan and low dose hydrochlorothiazide (12.5 mg). Your doctor will increase the amounts of losartan and hydrochlorothiazide step by step until the dose that is right for you has been achieved.

When to take it

HYZAAR/FORTZAAR can be taken with or without food. For convenience and to help you remember, try to take HYZAAR/FORTZAAR at the same time each day.

How long to take it

Take HYZAAR/FORTZAAR every day, exactly as your doctor has instructed. It is important to continue taking HYZAAR/FORTZAAR for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

If you forget to take it

Try to take HYZAAR/FORTZAAR daily as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule.

If you take too much (overdose)

In case of an overdose, contact your doctor immediately so that medical attention may be given promptly.

While you are taking HYZAAR/FORTZAAR

Things you must do

- Take your medicine exactly as your doctor has told you.

- Tell all the doctors, dentists and pharmacists treating you that you are taking HYZAAR/FORTZAAR.
- Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give HYZAAR/FORTZAAR to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Use in pregnancy and breast-feeding

The use of HYZAAR/FORTZAAR while you are pregnant or breast-feeding is not recommended. HYZAAR/FORTZAAR can cause harm or death to an unborn baby. Talk to your doctor about other ways to lower your blood pressure if you plan to become pregnant. If you get pregnant while taking HYZAAR/FORTZAAR tell your doctor right away.

Use in children

There is no experience with the use of HYZAAR/FORTZAAR in children. Therefore, HYZAAR/FORTZAAR should not be given to children.

Use in the elderly

In general, HYZAAR/FORTZAAR works equally well in, and is equally well tolerated by most older and younger adult patients. Most older patients require the same dose as younger patients. Older patients should begin treatment with HYZAAR 50/12.5 mg tablets.

Use in Black patients with high blood pressure and a thickening of the left ventricle.

In a study in patients with high blood pressure and a thickening of the left chamber of the heart, losartan was shown to decrease the risk of stroke and heart attack, and help patients live longer.

However, in this study, these benefits, when compared to another antihypertensive medicine called atenolol, did not apply to Black patients.

Can I drive or operate machinery while using HYZAAR/FORTZAAR?

Almost all patients can, but you should not perform tasks which may require special attention (for example, driving an automobile or operating dangerous machinery) until you know how you tolerate your medicine.

Side effects

Any medicine may have unintended or undesirable effects, so-called side effects. In most patients, HYZAAR/FORTZAAR is well tolerated. Side effects may include nausea, vomiting, cramping, diarrhea, constipation, headache, weakness, dizziness, fatigue, hives, rash, taste alteration, transient blurred vision, or increased sensitivity of the skin to sun. Another side effect may be a feeling of dizziness or lightheadedness due to a sudden drop in blood pressure when standing up quickly. Your doctor or pharmacist has a more complete list. Tell your doctor or pharmacist promptly about these or any other unusual symptoms.

If you develop an allergic reaction involving swelling of the face, lips, throat and/or tongue which may cause difficulty in breathing or swallowing, stop taking HYZAAR/FORTZAAR and contact your doctor immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

How can I learn more about HYZAAR/FORTZAAR and my condition?

You may obtain further information from your physician or pharmacist, who has more detailed information about the product and your condition.

Storage and disposal of HYZAAR/FORTZAAR

Storage

Store HYZAAR/FORTZAAR at room temperature.

Keep the container tightly closed. Do not open the blister pack until you are ready to take the medicine.

Keep all medicines safely away from children.

Disposal

Do not use this medicine after the month and year shown by the four numbers following EX (or EXP) on the container. The first two numbers indicate the month; the last two numbers indicate the year.

You may obtain further information from your doctor or pharmacist, who has more detailed information.

Product description

What it looks like

HYZAAR is available as 50/12.5 mg or 100/12.5 mg tablets. FORTZAAR is available as 100/25mg.

HYZAAR TABLET (losartan potassium 50mg/hydrochlorothiazide 12.5mg):

Yellow oval shaped film-coated tablet. One side plain, the other side imprinted 717. HYZAAR TABLET is available in blister packs of 30's/box.

HYZAAR TABLET 100/12.5MG (losartan potassium 100mg/hydrochlorothiazide 12.5mg): White to off-white, oval, film-coated tablet with '745' debossed on one side and plain on the other. HYZAAR TABLET 100/12.5MG is available in blister packs of 30's/box.

FORTZAAR TABLET (losartan potassium 100mg/hydrochlorothiazide 25mg): A light yellow, oval shaped, film-coated tablet with '747' on one side and plain on the other. FORTZAAR TABLET is available in blister packs of 30's/box.

Ingredients

Active ingredients: HYZAAR TABLET (losartan potassium and hydrochlorothiazide) is a yellow film-coated oval shaped tablet which contains 50 mg of losartan potassium and 12.5 mg of hydrochlorothiazide as the active ingredients.

HYZAAR TABLET 100/12.5MG (losartan potassium and hydrochlorothiazide) is a white to off-white film-coated oval shaped tablet which contains 100 mg of losartan potassium and 12.5 mg of hydrochlorothiazide as the active ingredients.

FORTZAAR TABLET (losartan potassium and hydrochlorothiazide) is a light yellow film-coated oval shaped tablet which contains 100 mg of losartan potassium and 25 mg of hydrochlorothiazide as the active ingredients.

Inactive ingredients: In addition, HYZAAR TABLET, HYZAAR TABLET 100/12.5MG and FORTZAAR TABLET contain the following inactive ingredients: microcrystalline cellulose, lactose hydrous, pregelatinized starch, magnesium stearate, hydroxypropyl cellulose, hypromellose.

Although HYZAAR/FORTZAAR contains a very small amount of potassium, it cannot replace potassium supplements. If your doctor has prescribed potassium supplements, continue to follow his advice.

MAL numbers:

HYZAAR TABLET:
MAL19990960AR

HYZAAR TABLET 100/12.5 MG:
MAL06081219AR

FORTZAAR TABLET:
MAL20013017AR

Product Manufacturer:

Merck Sharp & Dohme Ltd.
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Northumberland, NE23 3JU,
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Product Registration Holder:

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