

XYCOVAA FILM-COATED TABLET

Losartan Potaasium (50mg, 100mg)

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What Xycovaa is used for

Xycovaa is an angiotensin II receptor antagonist which lowers 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 Xycovaa to help lower the risk of cardiovascular events, such as stroke. Xycovaa also provides kidney protection by delaying the worsening of kidney disease in type 2 diabetic patients with protein in their urine (proteinuria). Kidney disease can be measured by testing the urine for protein.

How Xycovaa works

Xycovaa works by widening your blood vessels to make it easier for the heart to pump blood to all parts of your body. This helps to reduce high blood pressure. Xycovaa also helps to lower the risk of cardiovascular events, such as stroke, in patients with high blood pressure and a thickening of the left ventricle of the heart. In addition to these blood pressure effects, Xycovaa also helps protect your kidneys if you have type 2 diabetes with protein in the urine.

Before you take Xycovaa

When you must not use it

Do not take Xycovaa if you:

- are allergic (hypersensitive) to Losartan Potassium or any ingredients in this medicine.
- have diabetes and are taking a medicine called aliskiren to reduce blood pressure.

Before start to use it

Tell your doctor or pharmacist if you:

- have or have had any medical problems you and about any allergies.
- have recently suffered from excessive vomiting or diarrhea
- have liver or kidney disease
- are taking other drugs that may increase serum potassium

Taking other medicines

In general, Xycovaa does not interact with food or other medicines you may be taking. 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 important to tell your doctor if you are taking

- potassium supplements
- potassium-sparing agents
- salt substitutes containing potassium or other drugs that may increase serum potassium (e.g. trimethoprim-containing products),
- certain pain and arthritis medicines
- other blood pressure medicines
- lithium (a drug used to treat a certain kind of depression)
- grapefruit juice (which should be avoided while taking Xycovaa)

How to take Xycovaa

How much to take

Your doctor will decide on the appropriate dose of Xycovaa, depending on your condition and whether you are taking other medicines.

High Blood Pressure

The usual dose of Xycovaa for most patients with high blood pressure is 50 mg taken once a day to control blood pressure over the 24-hour period.

The usual dose of Xycovaa for patients with high blood pressure with a thickening of the left ventricle of the heart is 50 mg taken once a day. The dose may be increased to 100 mg taken once daily.

Type 2 Diabetes with Protein in the Urine

The usual dose of Xycovaa for most patients is 50 mg taken once a day. The

dose may be increased to 100 mg taken once daily.

When to take it

Take Xycovaa every day, exactly as your doctor has instructed.

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

How long to take it

It is important to continue taking Xycovaa 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 Xycovaa 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

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

While you are taking Xycovaa

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 Xycovaa.
- 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 Xycovaa to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Although Xycovaa contains a very small amount of potassium, it cannot replace potassium supplements. If your doctor has

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prescribed potassium supplements, continue to follow his advice.

Use in pregnancy and breast-feeding

The use of Xycovaa while you are pregnant or breast-feeding is not recommended. Xycovaa 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 Xycovaa tell your doctor right away.

Use in children

Xycovaa has been studied in children. For more information, talk to your doctor.

Use in the elderly

Xycovaa 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.

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, Xycovaa 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 Xycovaa?

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. Some patients may experience dizziness, fatigue, lightheadedness, rash, hives, taste alteration, vomiting or increased sensitivity of the skin to sun. Your doctor or pharmacist has a more complete list.

Tell your doctor or pharmacist promptly about these or any other unusual symptom.

Some patients, especially those with type 2 diabetes with protein in the urine, may also develop increased levels of potassium in their blood. If you have kidney disease and type 2 diabetes with protein in the urine, and/or are taking potassium supplements, potassium-sparing agents or salt substitutes containing potassium, talk to your doctor.

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 Xycovaa 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 visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Xycovaa

Storage

- Store below 30°C. Protect from light and moisture.
- 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 on packaging
- You may obtain further information from your doctor or pharmacist, who has more detailed information.

Product Description

What it looks like

Xycovaa Film-Coated Tablet 50 mg:

White, oval, normal convex film-coated tablet with “Z” marking on one side and plain on reverse.

Xycovaa Film-Coated Tablet 100 mg:

White, round, normal convex film-coated tablet with “Z” marking on one side and plain on reverse.

Available in blister strips of 10’s in packing of 30 per box

Ingredients

- Active ingredient:
Losartan Potassium

- Inactive ingredients:

Tablet core:

Microcrystalline Cellulose, Lactose Monohydrate, Starch, Colloidal Silicon Dioxide, Magnesium Stearate

Film coat

Hydroxypropyl Cellulose, Hypromellose, Purified Stearic Acid, Titanium Dioxide

MAL Number.:

Xycovaa Film-Coated Tablet 50 mg:

MALxxxxxxxA

Xycovaa Film-Coated Tablet 100 mg:

MALxxxxxxxA

Manufacturer and Product

Registration Holder

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