

COZAAR™ XQ

Amlodipine camsylate/losartan potassium (5/50 mg, 5/100 mg) tablet

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What COZAAR XQ is used for

COZAAR XQ is a combination of an angiotensin II receptor antagonist (losartan) and a calcium channel blocker (amlodipine).

COZAAR XQ may be used to lower high blood pressure (hypertension) in adults when one medicine to lower your high blood pressure is not enough.

Your doctor has prescribed COZAAR XQ because you have a condition known as hypertension (high blood pressure).

How COZAAR XQ works

COZAAR XQ 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.

The losartan ingredient of COZAAR XQ lowers blood pressure by specifically blocking a substance called angiotensin II.

Angiotensin II normally tightens your blood vessels. Treatment with losartan allows them to relax. The amlodipine ingredient of COZAAR XQ lowers blood pressure by specifically blocking calcium ions from entering the cells of the blood vessel walls and heart. The flow of calcium ions into these cells causes your blood vessels to tighten. Amlodipine allows them to relax. 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 COZAAR XQ

Information for Patients with High Blood Pressure

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 life-style. 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 COZAAR XQ.

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.

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Before you take COZAAR XQ

When you must not take it

Do not take COZAAR XQ if you are allergic to any of its ingredients.

Do not take COZAAR XQ if you have diabetes and are taking a medicine called aliskiren to reduce blood pressure.

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, kidney, or heart disease.

Taking other medicines

In general, COZAAR XQ 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 or salt substitutes containing potassium. Also tell your doctor if you are taking certain pain and arthritis medicines, other blood pressure medicines, or lithium (a drug used to treat a certain kind of depression).

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

How to take COZAAR XQ

How much to take

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

When to take it

Take COZAAR XQ every day, exactly as your doctor has instructed.

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

How long to take it

It is important to continue taking COZAAR XQ 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 COZAAR XQ 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 COZAAR XQ

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 COZAAR.
- 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 COZAAR 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 COZAAR XQ while you are pregnant or breast-feeding is not recommended. COZAAR XQ may cause harm or death to your 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 COZAAR XQ, tell your doctor right away.

Use in children

There is no experience with the use of COZAAR XQ in children. Therefore, COZAAR XQ should not be given to children.

Use in the elderly

COZAAR XQ works equally well in and is equally well tolerated by older and younger adult patients. Older patients may require a lower starting dose of the amlodipine ingredient than younger patients.

Can I drive or operate machinery while using COZAAR XQ?

There have been side effects reported with COZAAR XQ that may affect your ability to drive

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or operate machinery.
Individual responses to COZAAR XQ may vary (see “Side effects”).

Side effects

Any medicine may have unintended or undesirable effects, so-called side effects. Some patients may experience dizziness, headache, fatigue, extreme sleepiness, lightheadedness, flushing (hot or warm feeling in your face), swelling of your legs or ankles, chest pain, arrhythmia (irregular heartbeat), heart palpitations (very fast heartbeat), rash, hives, taste alteration, stomach pain, nausea, 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 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 COZAAR XQ 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 COZAAR XQ and my condition?

You may obtain further information from your physician or pharmacist, who have more detailed information about your condition and COZAAR XQ.

Storage and Disposal of COZAAR XQ

Storage

Store COZAAR XQ at temperatures below 30°C (86°F) and protect from moisture.

Store in the original package. 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.

Product Description

What it looks like

COZAAR XQ 5/50MG: white, modified capsule shaped, film-coated tablet, debossed with ‘222’ on one side and plain on the other side.

COZAAR XQ 5/100mg: pink, modified capsule shaped, film-coated tablet, debossed with ‘331’ on one side and the plain on the other side.

Ingredients

Active ingredients:
COZAAR XQ (amlodipine camsylate/losartan potassium) is a film-coated tablet which contains the active ingredients amlodipine camsylate and losartan potassium in the following combinations:

- 5/50 mg tablets: white, modified capsule shaped tablet containing amlodipine camsylate 7.84 mg (equivalent to 5 mg amlodipine) and losartan potassium 50 mg
- 5/100 mg tablets: pink, modified capsule shaped tablet containing amlodipine camsylate 7.84 mg (equivalent to 5 mg amlodipine) and losartan potassium 100 mg

Inactive ingredients:

In addition, COZAAR XQ contains the following inactive ingredients: butylated hydroxytoluene, sodium starch glycolate, microcrystalline cellulose, D-mannitol, povidone, crospovidone, magnesium stearate, hypromellose, hydroxypropylcellulose, titanium oxide, and talc. COZAAR XQ 5/100 mg tablets also contain iron oxide red and iron oxide yellow.

MAL number

COZAAR XQ 5/50 mg tablet: MAL12025077ACR

COZAAR XQ 5/100 mg tablet: MAL12025078ACR

Manufacturer

Hanmi Pharm. Co., Ltd.

(Paltan site)

893-5, Hajeo-ri, Paltan-myeon, Hwaseong-si, Gyeonggi-do,

COZAAR™ XQ

Amlodipine camsylate/losartan potassium (5/50 mg, 5/100 mg) Tablet

445-913, South Korea.

Product Registration

Holder

MERCK SHARP & DOHME

(MALAYSIA) SDN. BHD.

T2-9, Jaya 33, No. 3 (Lot 33)

Jalan Semangat, Seksyen 13

46100 Petaling Jaya, Selangor,

Malaysia.

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26/12/2014(version 092013)

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