Patient Information Leaflet

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

AMZAAR® 5/50 Tablets

AMZAAR® 5/100 Tablets

amlodipine (as amlodipine camsylate)

losartan potassium

Contains sugar (mannitol)

AMZAAR 5/50 mg Tablets contain 40 mg mannitol per tablet

AMZAAR 5/100 mg Tablets contain 40 mg mannitol per tablet

Read all of this leaflet carefully before you start taking AMZAAR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- AMZAAR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What AMZAAR is and what it is used for

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

AMZAAR may be used to lower high blood pressure (hypertension) in adults if you are taking the same doses of the separate medicines.

Your doctor has prescribed AMZAAR because you have hypertension (high blood pressure).

2. What you need to know before you take AMZAAR

Do not take AMZAAR:

- if you are hypersensitive (allergic) to amlodipine, losartan or any of the other ingredients of AMZAAR (see Section 6).
- if you have previously been treated with a medication in the same group of medicines as AMZAAR (angiotensin receptor antagonists) or with a medication in the group of medicines known as ACE inhibitors and have had allergic reactions with swelling of the face, lips, tongue, and/or throat with difficulty in swallowing or breathing (angioedema).
- if you have hereditary or idiopathic angioedema (swelling of the face, lips, mouth, tongue or throat with or without difficulty in swallowing or breathing) while taking AMZAAR or a similar medicine.
- if you have hypertrophic obstructive cardiomyopathy, a heart disorder in which the walls of the ventricles (lower heart chambers) thicken (hypertrophy) and become stiff, and the thickened muscle blocks the flow of blood out of the heart.
- if you have severe kidney disease.
- if you have liver disease.
- if you have narrowing of the blood vessels to both kidneys or to a single kidney.

- if you have aortic stenosis, a narrowing of the aortic valve opening between the left ventricle (large pumping chamber of the heart) and the aorta (the main artery leading away from the heart).
- if you are taking diuretics (water pills) that cause your body to retain potassium such as spironolactone, triamterene and amiloride.
- if you have porphyria.
- Lithium therapy: Concomitant administration with AMZAAR may lead to toxic blood concentrations of lithium.
- if you are pregnant or breastfeeding (see Pregnancy and breastfeeding).
- if you are also taking a medicine called aliskiren. You can ask your doctor if you are not sure.
- if you have moderate to severe kidney disease and are prescribed a course of an antibiotic of the fluoroquinolone class for an infection. Ask your doctor what other medicines than AMZAAR you should receive to control your blood pressure or if you should receive a different antibiotic.

Warnings and precautions

Take special care with AMZAAR:

- 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 diarrhoea.
- It is particularly important to tell your doctor if you have liver, kidney, or heart disease. AMZAAR may not be appropriate for you if you have liver function problems.
- If you have kidney disease and type 2 diabetes with protein in the urine, and/or are taking potassium supplements, potassium-sparing agents, salt substitutes containing potassium, or other medicines that may increase serum potassium talk to your doctor (see Section 2).

Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking AMZAAR. Your doctor will decide on further treatment. Do not stop taking AMZAAR on your own.

Children

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

Other medicines or substances and AMZAAR

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

In general, AMZAAR does not interact with food or other medicines you may be taking. You should, however, tell your doctor about all medicines that you are taking or plan to take, including those obtained without a prescription, and grapefruit juice, which should be avoided while taking AMZAAR.

It is important to tell your doctor if you are taking potassium supplements, potassium-sparing agents, salt substitutes containing potassium or other medicines that may increase serum potassium (e.g., trimethoprim-containing products).

Also tell your doctor if you are taking certain pain and arthritis medicines, other blood pressure medicines, or lithium (a medicine used to treat a certain kind of depression).

Taking a course of a fluoroquinolone antibiotic with AMZAAR can cause acute kidney injury, especially if you have moderate to severe kidney disease, or you are elderly.

Should your doctor prescribe an antibiotic medicine for an infection, tell them that you are taking AMZAAR.

AMZAAR with food and drink

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

Pregnancy and breastfeeding

The use of AMZAAR while you are pregnant or breastfeeding is contraindicated.

AMZAAR 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 AMZAAR, tell your doctor right away.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking AMZAAR.

Driving and using machinery

There have been side effects reported with AMZAAR that may affect your ability to drive or operate machinery. Individual responses to AMZAAR may vary (see Section 5). It is not always possible to predict to what extent AMZAAR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which AMZAAR affects them.

AMZAAR contains mannitol.

3. HOW TO TAKE AMZAAR

Do not share medicines prescribed for you with any other person.

Take AMZAAR every day, exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are not sure.

Your doctor will decide on the appropriate dose of AMZAAR, depending on your condition and whether you are taking other medicines. Your doctor will decide how long your treatment with AMZAAR will last. It is important to continue taking AMZAAR for as long as your doctor prescribes it.

If you have the impression that the effect of AMZAAR is too strong or too weak, tell your doctor or pharmacist.

If you take more AMZAAR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, consult the nearest hospital or poison control centre.

If you forget to take AMZAAR

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

4. POSSIBLE SIDE EFFECTS

AMZAAR can have side effects.

Not all side effects reported for AMZAAR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AMZAAR, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking AMZAAR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction involving swelling of the face, lips, throat and/or tongue which may cause difficulty in breathing or swallowing
- swelling of your legs or ankles
- rash
- hives.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to AMZAAR. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain
- dysrhythmia (irregular heartbeat)
- heart palpitations (very fast heartbeat).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- intestinal angioedema (a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea)
- dizziness
- headache
- fatigue
- extreme sleepiness
- light-headedness
- flushing (hot or warm feeling in your face)
- taste alteration
- stomach pain
- nausea

- vomiting
- increased sensitivity of the skin to sun.

You may also develop increased levels of potassium in your blood.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of AMZAAR.

5. How to store AMZAAR

Store all medicines out of reach of children.

Store at or below 30 °C. Keep blister in carton until required for use. Protect from moisture.
Do not open the blister pack until you are ready to take AMZAAR.
Do not use AMZAAR after the month and year shown by the four numbers following EXP.: on the container. The first two numbers indicate the month; the last two numbers indicate the year.

Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

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

AMZAAR 5/50 mg Tablets: contain amlodipine camsylate 7,84 mg (equivalent to 5 mg amlodipine) and losartan potassium 50 mg.
AMZAAR 5/100 mg Tablets: contain amlodipine camsylate 7,84 mg (equivalent to 5 mg amlodipine) and losartan potassium 100 mg.

In addition, AMZAAR contains the following inactive ingredients: microcrystalline cellulose, crospovidone, hydroxypropylcellulose, butylated hydroxytoluene, hypromellose, magnesium stearate, D-mannitol, povidone, sodium starch glycolate, talc and titanium oxide.

AMZAAR 5/100 mg Tablets also contain iron oxide red and iron oxide yellow.

AMZAAR contains sugar (mannitol).

What AMZAAR looks like and contents of the pack

AMZAAR 5/50: White modified capsule shaped film-coated tablet, debossed with 222 on one side and the other side is plain.

AMZAAR 5/100: Pink modified capsule shaped film-coated tablet, debossed with 331 on one side and the other side is plain.

AMZAAR is packaged in push-through aluminium blisters of 30 tablets. The material used to fabricate the blister cavity is a laminate consisting of silver polyvinylchloride (PVC)/aluminium/polyamide film. The lidding material is a push through aluminium foil with heat seal coating one side and print primer on the other. The blisters are packed in a carton.

Holder of Certificate of Registration

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