PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

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

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

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.

1. WHAT AMZAAR CONTAINS

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, hydroxypropyl cellulose, butylated hydroxytoluene, hypromellose, magnesium stearate, D-mannitol, povidone, sodium starch glycolate, talc and titanium oxide.

AMZAAR contains sugar (mannitol).

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

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

2. WHAT AMZAAR IS USED FOR

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).

3. 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 **What AMZAAR CONTAINS**).
- 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.

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.

Use in children

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

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 **Do not take AMZAAR** and **Taking other medicines with AMZAAR**).

Taking 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 **POSSIBLE SIDE EFFECTS**).

Taking other medicines with AMZAAR

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. 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).

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

4. HOW TO TAKE AMZAAR

Take AMZAAR every day, exactly as your doctor has instructed. Your doctor will decide on the appropriate dose of AMZAAR, depending on your condition and whether you are taking other medicines. It is important to continue taking AMZAAR for as long as your doctor prescribes it.

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 a dose of 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.

5. 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 this medicine, please consult your doctor, pharmacist or other healthcare professional 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:

- 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.

6. STORING AND DISPOSING OF AMZAAR

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 following EXP.: on the container.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF AMZAAR

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.

8. IDENTIFICATION OF AMZAAR

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.

9. REGISTRATION NUMBERS

AMZAAR 5/50: 46/7.1.3/0559

AMZAAR 5/100: 46/7.1.3/0560

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Organon South Africa (Pty) Ltd

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11. DATE OF PUBLICATION

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