PATIENT INFORMATION LEAFLET

Scheduling status

S3

AMIZART 50 mg film-coated tablets

AMIZART 100 mg film-coated tablets

Losartan potassium

AMIZART 50 mg contains 70,0 mg of lactose monohydrate per film-coated tablet

AMIZART 100 mg contains 140,0 mg of lactose monohydrate per film-coated tablet

Read all of this leaflet carefully before you start taking AMIZART

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- AMIZART 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 AMIZART is and what it is used for

Losartan belongs to a group of medicines known as angiotensin II receptor antagonists.

Angiotensin II is a substance produced in the body, which binds to receptors in blood vessels, causing them to tighten. This results in an increase in blood pressure. Losartan prevents the binding of angiotensin II to these receptors, causing the blood vessels to relax which in turn lowers the blood pressure. Losartan slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

AMIZART is used:

- to treat patients with high blood pressure (hypertension).
- to protect the kidney in hypertensive type 2 diabetic patients and in patients with a condition in which urine contains an abnormal amount of protein.

2. What you need to know before you take AMIZART

Do not take AMIZART:

- if you are allergic to losartan, or to any of the other ingredients of this medicine (listed in section 6).
- if you have developed swelling of the face, lips, mouth, tongue or throat and giant wheals on your skin when previously taking medicines called angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) – you should never take these medicines again.
- if your doctor has told you that the thickness of your heart muscle is abnormally increased (hypertrophic obstructive cardiomyopathy (HOCM)).
- if you suffer from obstruction of blood vessels to your heart or kidneys.
- if you have severe kidney function problems.
- if you are currently taking potassium sparing diuretics (“water tablets”) containing spironolactone, triamterene or amiloride.
- if you have porphyria (a rare hereditary disease).
- if you are currently taking lithium (used to treat some types of depression).

- if you are pregnant, are considering becoming pregnant or are breastfeeding. A switch to a suitable alternative treatment should be carried out in advance of planned pregnancy.
- if you suffer from severe liver disease or biliary obstruction (a problem with the drainage of the bile from the gall bladder).
- if you are currently taking aliskiren-containing medicine.
- if you are taking a fluoroquinolone antibiotic (used to treat a variety of illnesses such as respiratory and urinary tract infections).
- if you have kidney problems or are elderly.

Warnings and precautions

Tell your doctor or healthcare provider before taking AMIZART:

- if you have had a history of angioedema (swelling of the face, lips, throat, and/or tongue) (see also section 4 “Possible side effects”).
- if you suffer from excessive vomiting or diarrhoea leading to an extreme loss of fluid and/or if you receive diuretics (medicines that increase the amount of water that you pass out through your kidneys) or are under dietary salt restriction leading to an extreme loss of fluid and salt in your body (see section 3 “How to take AMIZART”).
- if you are known to have narrowing or blockage of the blood vessels leading to your kidneys or if you have received a kidney transplant recently.
- if your liver function is impaired (see section 2 “Do not take AMIZART” and 3 “How to take AMIZART”).
- if you suffer from heart failure with or without renal impairment or concomitant severe life-threatening cardiac arrhythmias*.* Special caution is necessary when you are treated with a ß-blocker concomitantly.
- if you have problems with your heart valves or heart muscle.

- if you suffer from coronary heart disease (caused by a reduced blood flow in the blood vessels of the heart) or from cerebrovascular disease (caused by a reduced blood circulation in the brain).
- if you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland).
- if you are taking any of the following medicines used to treat high blood pressure:
  - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes related kidney problems
  - aliskiren.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading “Do not take AMIZART”.

- if you are taking other medicines that may increase serum potassium (see section 2 “Other medicines and AMIZART”).
- If you are taking fluoroquinolones (antibiotics to treat infections).

Children and adolescents

AMIZART is not recommended for use in children suffering from kidney or liver problems, as limited data are available in these patient groups.

Other medicines and AMIZART

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

Tell your doctor if you are taking:

- potassium supplements, potassium-containing salt substitutes, potassium-sparing medicines such as certain diuretics (spironolactone, triamterene or amiloride), or other

medicines that may increase serum potassium (e.g. heparin, trimethoprim-containing medicines), as the combination with AMIZART is not advisable.

Take particular care if you are taking the following medicines while under treatment with AMIZART:

- other blood pressure lowering medicines as they may additionally reduce your blood pressure.

  Blood pressure may also be lowered by one of the following medicines/class of medicines: tricyclic antidepressants, antipsychotics, baclofen, amifostine.
- non-steroidal anti-inflammatory drugs such as indomethacin, including COX-2-inhibitors (medicines that reduce inflammation, and can be used to help relieve pain) as they may reduce the blood pressure lowering effect of losartan.

Your doctor may need to change your dose and/or to take other precautions:

- if you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take AMIZART” and “Warnings and precautions”).
- if your kidney function is impaired, the concomitant use of these medicines may lead to a worsening of the kidney function.

Lithium containing medicines should not be taken in combination with losartan without close supervision by your doctor. Special precautionary measures (e.g. blood tests) may be appropriate.

Taking AMIZART with food and drink

AMIZART may be taken with or without food.

Pregnancy and breastfeeding

Pregnancy

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

You should not take AMIZART if you are pregnant as it may cause serious harm to your baby.

Breastfeeding

Tell your doctor if you are breastfeeding or about to start breastfeeding.

You should not take AMIZART if you are breastfeeding and your doctor may choose another treatment for you if you wish to breastfeed.

Driving and using machines

AMIZART is unlikely to affect your ability to drive or use machines. However, as with many other medicines used to treat high blood pressure, losartan may cause dizziness or drowsiness in some people. If you experience dizziness or drowsiness, you should consult your doctor before attempting such activities.

Important information about some of the ingredients of AMIZART

AMIZART contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking AMIZART**.**

3. How to take AMIZART

Always take AMIZART exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are not sure.

Your doctor will decide on the appropriate dose of AMIZART, depending on your condition and whether you are taking other medicines. It is important to continue taking AMIZART for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

The usual dose is 50 mg losartan (one tablet AMIZART 50 mg) once a day. The maximal blood pressure lowering effect should be reached 3 - 6 weeks after beginning treatment.

In some patients, the dose may later be increased to 100 mg losartan (two tablets AMIZART 50 mg or one tablet of AMIZART 100 mg) once daily.

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

Administration

The tablets should be swallowed whole with a glass of water. You should try to take your daily dose at about the same time each day. It is important that you continue to take AMIZART until your doctor tells you otherwise.

If you take more AMIZART than you should

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

If you forget to take AMIZART

Do not take/receive a double dose to make up for a forgotten tablet.

4. Possible side effects

AMIZART can have side effects.

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

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

- A severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to AMIZART. 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:

Frequent side effects

- dizziness
- low blood pressure (especially after excessive loss of water from the body within blood vessels e.g. in patients with severe heart failure or under treatment with high dose diuretics)
- dose-related orthostatic effects such as lowering of blood pressure appearing when rising from a lying or sitting position
- debility (feeling weak and loss of energy)
- fatigue
- too little sugar in the blood (hypoglycaemia)
- too much potassium in the blood (hyperkalaemia)
- changes in kidney function including kidney failure
- reduced number of red blood cells (anaemia)
- increase in blood urea, serum creatinine and serum potassium in patients with heart failure.

Less frequent side effects

- somnolence
- headache
- sleep disorders
- feeling of increased heart rate (palpitations)
- severe chest pain (angina pectoris)
- shortness of breath (dyspnoea)

- abdominal pain
- obstipation
- diarrhoea
- nausea
- vomiting
- hives (urticaria)
- itching (pruritus)
- rash
- localised swelling (oedema)
- cough
- hypersensitivity
- angioedema (swelling of larynx and glottis)
- inflammation of blood vessels (vasculitis including Henoch-Schönlein purpura)
- numbness or tingling sensation (paraesthesia)
- fainting (syncope)
- very rapid and irregular heartbeat (artrial fibrillation)
- brain attack (stroke)
- inflammation of the liver (hepatitis)
- elevated blood alanine aminotransferase (ALT) levels, usually resolved upon discontinuation of treatment.

Frequency unknown (frequency cannot be estimated from the available data)

- reduced number of thrombocytes
- migraine
- liver function abnormalities
- muscle and joint pain
- flu-like symptoms
- back pain and urinary tract infection

- increased sensitivity to the sun (photosensitivity)
- unexplained muscle pain with dark (tea-coloured) urine (rhabdomyolysis)
- impotence
- inflammation of the pancreas (pancreatitis)
- low levels of sodium in the blood (hyponatraemia)
- depression
- generally feeling unwell (malaise)
- ringing, buzzing, roaring, or clicking in the ears (tinnitus)
- disturbed taste (dysgeusia).

Side effects in children are similar to those seen in adults.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of AMIZART**.**

5. How to store AMIZART

Store all medicines out of reach of children.

Store at or below 30°C, in the original package. Keep blisters in the carton until required for use.

Do not use AMIZART after the expiry date, which is stated on the carton. The expiry date refers to the last day of that month.

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

What AMIZART contains

AMIZART tablets contain 50 mg or 100 mg losartan potasium.

The other ingredients are microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, purified talc and magnesium stearate.

The film-coating contains hypromellose, titanium dioxide, talc and polyethylene glycol.

What AMIZART looks like and contents of the pack

AMIZART 50 mg is a white to off-white, oval shaped, biconvex, film-coated tablet, debossed “50” on one side and plain on other side.

AMIZART 100 mg is a white to off-white, almond shaped, biconvex, film-coated tablet, debossed “100” on one side and plain on other side.

The film-coated tablets are packed in aluminium/aluminium foil blister strips. The blister strips are packed in cartons containing 28 or 30 tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration

Smart Pharmaceuticals (Pty) Ltd

247 Voortrekker Road

Kraaifontein, Cape Town

7570

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