Package leaflet: Information for user

***Sortiva*® 25 mg film-coated tablets**
***Sortiva*® 50 mg film-coated tablets**
***Sortiva* Forte® 100 mg film-coated tablets**
Losartan potassium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any of the side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. WHAT *Sortiva* IS AND WHAT IT IS USED FOR

Losartan (***Sortiva***) 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.

***Sortiva* is used:**
- To treat patients with high blood pressure (hypertension) in adults and in children and adolescents 6-18 years of age.
- To protect the kidney in hypertensive type 2 diabetic patients with laboratory evidence of impaired renal function and proteinuria ≥ 0.5 g per day (a condition in which urine contains an abnormal amount of protein).
- To treat patients with chronic heart failure when therapy with specific medicines called angiotensin-converting-enzyme inhibitors (ACE inhibitors, medicine used to lower high blood pressure) is not considered suitable by your doctor. If your heart failure has been stabilised with an ACE inhibitor you should not be switched to losartan.
- In patients with high blood pressure and a thickening of the left ventricle, ***Sortiva*** has been shown to decrease the risk of stroke ("LIFE indication").

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE *Sortiva*

Do not take *Sortiva*
- If you are allergic to losartan or to any of the other ingredients of this medicine (listed in section 6).
- If you are more than 3 months pregnant. (It is also better to avoid ***Sortiva*** in early pregnancy- see Pregnancy),
- If your liver function is severely impaired.

Warnings and precautions
Talk to your doctor or pharmacist before taking *Sortiva*.
You must tell your doctor if you think you are (or might become) pregnant. ***Sortiva*** is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).
It is important to tell your doctor before taking ***Sortiva***:
- 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 liver or kidney problems
- If you have recently suffered from severe vomiting or diarrhoea leading to an extreme loss of fluid and/or salt in your body.
- 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 'Dosage in special patient groups').
- 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 sections 2 "Do not take ***Sortiva***" and 3 "Dosage in special patient groups").
- 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 (e.g. aortic stenosis or outflow obstruction)
- 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 have a high level of potassium in your blood (hyperkalaemia)
- Dual blockage of Renin- Angiotensin System (RAS) with Angiotensin blockers, ACE inhibitors or Aliskiren is associated with increased risk of hypotension, hyperkalemia and changes in renal function (including acute renal failure) compared to monotherapy. Closely monitor blood pressure, renal function and electrolytes in patients on Losartan and other agents that affect RAS.

Children and adolescents
Sortiva has been studied in children. For more information, talk to your doctor.
Sortiva is not recommended for use in children suffering from kidney or liver problems, or children under 6 years old, as limited data are available in these patient groups.
Other medicines and *Sortiva*
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.
Take particular care if you are taking the following medicines while under treatment with ***Sortiva***:
- Other blood pressure lowering medicines as they may additionally reduce your blood pressure. Blood pressure may also be lowered by one of the following drugs/class of drugs: tricyclic antidepressants, antipsychotics, baclofen, amifostine.
- Lithium (used to treat certain types of mental illness)
- Medicines which retain potassium or may increase potassium levels (e.g. potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines such as certain diuretics [amiloride, triamterene, spironolactone] or heparin).
- Non-steroidal anti-inflammatory drugs such as indometacin, 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.
- Do not co-administer Aliskiren with Losartan if you are diabetic.
- Avoid use of Aliskiren with Losartan in patients with renal impairment (GFR<60 ml/min).

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.
***Sortiva* with food and drink**
Sortiva may be taken with or without food.
Pregnancy and breast-feeding
Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking ***Sortiva*** before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of ***Sortiva***. ***Sortiva*** is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.
Breast-Feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. ***Sortiva*** is not recommended for mothers who are breast feeding, and your doctor may choose another treatment for you if you wish to breast-feed. Especially if your baby is a newborn, or born prematurely.
Ask your doctor or pharmacist for advice before taking this medicine.
Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed.
Sortiva 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.

3. HOW TO TAKE *Sortiva*

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will decide on the appropriate dose of ***Sortiva***, depending on your condition and whether you are taking other medicines. It is important to continue taking ***Sortiva*** for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.
Adult patients with High Blood Pressure
Treatment usually starts with 50 mg losartan (one tablet ***Sortiva*** 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 once daily. If you have the impression that the effect of losartan is too strong or too weak, please talk to your doctor or pharmacist.
Use in children and adolescents (6 to 18 years old)
The recommended starting dose in patients who weigh between 20 and 50 kg is 0.7 mg of losartan per kg of body weight administered once a day. The doctor may increase the dose if blood pressure is not controlled.
Adult patients with high blood pressure and Type 2 diabetes
Treatment usually starts with 50 mg losartan (one tablet ***Sortiva*** 50 mg) once a day. The dose may later be increased to 100 mg losartan once daily depending on your blood pressure response.
Losartan may be administered with other blood pressure lowering medicines (e.g. diuretics, calcium channel blockers, alpha- or beta-blockers, and centrally acting agents) as well as with insulin and other commonly used medicines that decrease the level of glucose in the blood (e.g. sulfonylureas, glitazones and glucosidase inhibitors).
Adult Patients with Heart Failure
Treatment usually starts with 12.5 mg losartan once a day. Generally, the dose should be increased weekly step-by-step (i.e., 12.5 mg daily, 25 mg daily, 50 mg daily) to the usual maintenance dose of 50 mg once daily, as tolerated by the patient.
A maximum dose of 150 mg losartan (for example, three tablets of ***Sortiva*** 50 mg or one tablet each of ***Sortiva*** Forte 100mg and ***Sortiva*** 50 mg) once daily may be used.
In the treatment of heart failure, losartan is usually combined with a diuretic (medicine that increases the amount of water that you pass out through your kidneys) and/or digitalis (medicine that helps to make the heart stronger and more efficient) and/or a beta-blocker.
Dosage in special patient groups
The doctor may advise a lower dose, especially when starting treatment in certain patients such as those treated with diuretics in high doses, in patients with liver impairment, or in patients over the age of 75 years. The use of losartan is not recommended in patients with severe hepatic impairment (see section "Do not take ***Sortiva***").
Administration
The tablets should be swallowed 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 ***Sortiva*** until your doctor tells you otherwise.
If you take more *Sortiva* than you should
If you accidentally take too many tablets, contact your doctor immediately. Symptoms of overdose are low blood pressure, increased heartbeat, possibly decreased heartbeat.
If you forget to take *Sortiva*
If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten tablet. If you have any further questions on the use of this medicine, ask your doctor, pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
If you experience the following, stop taking losartan tablets 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 that may cause difficulty in swallowing or breathing).

This is a serious but rare side effect, which affects more than 1 out of 10,000 patients but fewer than 1 out of 1,000 patients. You may need urgent medical attention or hospitalization.
The following side effects have been reported with ***Sortiva***:
Common (may affect up to 1 in 10 people):
- Dizziness.
- Low blood pressure.
- Debility.
- 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.

Uncommon (may affect up to 1 in 100 people):
- Somnolence.
- Headache.
- Sleep disorders.
- Feeling of increased heart rate (palpitations).
- Severe chest pain (angina pectoris).
- 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 of diuretics).
- Dose-related orthostatic effects such as lowering of blood pressure appearing when rising from a lying or sitting position.
- Shortness of breath (dyspnoea).
- Abdominal pain.
- Obstipation.
- Diarrhoea.
- Nausea.
- Vomiting.
- Hives (urticaria).
- Itching (pruritus).
- Rash.
- Localised swelling (oedema),
- Cough.

Rare (may affect up to 1 in 1,000 people):
- Hypersensitivity.
- Angiooedema.
- Inflammation of blood vessels (vasculitis including Henöch-Schonlein purpura).
- Numbness or tingling sensation (paraesthesia).
- Fainting (syncope).
- Very rapid and irregular heartbeat (atrial fibrillation).
- Brain attack (stroke).
- Inflammation of the liver (hepatitis).
- Elevated blood alanine aminotransferase (ALT) levels, usually resolved upon discontinuation of treatment.

Not known (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).

Side effects in children are similar to those seen in adults.
If you get any of the side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE *Sortiva*

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton
Store below 30°C.

6. CONTENTS OF THE PACK AND FURTHER INFORMATION

What *Sortiva* contains
The active substance is losartan potassium.
Each ***Sortiva*** 25 mg tablet contains 25 mg of losartan potassium.
Each ***Sortiva*** 50 mg tablet contains 50 mg of losartan potassium.
Each ***Sortiva*** Forte tablet contains 100 mg of losartan potassium.
Excipients: Microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, purified talc, magnesium stearate, polysorbate, titanium dioxide, polyethylene glycol, hydroxypropyl methylcellulose, purified water.
What *Sortiva* looks like and contents of the pack
Sortiva is supplied as a film-coated tablet. In pack of 30 film coated tablets.

Marketing Authorization Holder and Manufacturer
SPIMACO
Al-Qassim pharmaceutical plant
Saudi Pharmaceutical Industries & Medical Appliances Corporation.
Saudi Arabia

This leaflet was last approved in January 2013.

Sortiva® is a trade mark
34SV381

To report any side effect(s)
- National Pharmacovigilance Centre (NPC):
  - Fax :+966-1-210-7398
  - E-mail: npc.drug@sfda.gov.sa
  - Website: www.sfda.gov.sa/npc

This is a medicament
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for your.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacists who sold the medicament.
- The doctor and the pharmacists are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children
Council of Arab Health Ministers
Union of Arab Pharmacists