

SORTIVA® H SPIMACO

Losartan Potassium and Hydrochlorothiazide
Sortiva H 100 mg/12.5 mg Film-coated Tablets
Sortiva H 50 mg/12.5 mg Film-coated Tablets
Sortiva H 100 mg/25 mg Film-coated Tablets
losartan potassium and hydrochlorothiazide

1. WHAT “Sortiva H” IS AND WHAT IT IS USED FOR

“Sortiva H” is a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide). 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. Hydrochlorothiazide works by making the kidneys pass more water and salt. This also helps to reduce blood pressure.

“Sortiva H” is indicated for the treatment of essential hypertension (high blood pressure).

2. BEFORE YOU TAKE “Sortiva H”

Do not take “Sortiva H”

- If you are allergic (hypersensitive) to losartan, hydrochlorothiazide or to any of the other ingredients in this medicine.
- If you are allergic (hypersensitive) to other sulfonamide-derived substances (e. g. other thiazides, some antibacterial drugs such as co-trimoxazole, ask your doctor if you are not sure).
- If you are more than 3 months pregnant. (It is also better to avoid “Sortiva H” in early pregnancy - see Pregnancy).
- If you have severely impaired liver function.
- If you have severely impaired kidney function or your kidneys are not producing any urine.
- If you have low potassium, low sodium or high calcium levels which cannot be corrected by treatment.
- If you are suffering from gout.

Take special care with “Sortiva H”

You must tell your doctor if you think you are (or might become) pregnant.

“Sortiva H” 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 H”:

- If you have previously suffered from swelling of the face, lips, throat or tongue.
- If you take diuretics (water pills).
- If you are on a salt-restricted diet.
- If you have or have had severe vomiting and/or diarrhoea.
- If you have heart failure.
- If your liver function is impaired (see section 2 “Do not take “Sortiva H””).
- If you have narrow arteries to your kidneys (renal artery stenosis) or only have one functioning kidney, or you have recently had a kidney transplant.
- If you have narrowing of the arteries (atherosclerosis), angina pectoris (chest pain due to poor heart function).
- If you have ‘aortic or mitral valve stenosis’ (narrowing of the valves of the heart) or ‘hypertrophic cardiomyopathy’ (a disease causing thickening of heart muscle).
- If you are diabetic.
- If you have had gout.
- If you have or have had an allergic condition, asthma or a condition that causes joint pain, skin rashes and fever (systemic lupus erythematosus).
- If you have high calcium or low potassium levels or you are on a low potassium diet.
- If you need to have an anaesthetic (even at the dentist) or before surgery, or if you are going to have tests to check your parathyroid function, you must tell the doctor or medical staff that you are taking losartan potassium and hydrochlorothiazide tablets.

- 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).

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Diuretic agents such as the hydrochlorothiazide contained in "*Sortiva H*" may interact with other medicines.

Preparations containing lithium should not be taken with "*Sortiva H*" without close supervision by your doctor.

Special precautionary measures (e.g. blood tests) may be appropriate if you take potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines, other diuretics ("water tablets"), some laxatives, medicines for the treatment of gout, medicines to control heart rhythm or for diabetes (oral agents or insulins).

It is also important for your doctor to know if you are taking

- Other medicines to reduce your blood pressure.
- Steroids.
- Medicines to treat cancer.
- Pain killers.
- Drugs for treatment of fungal infections arthritis medicines.
- Resins used for high cholesterol, such as cholestyramine.
- Medicines which relax your muscles.
- Sleeping tablets.
- Opioid medicines such as morphine.
- 'Pressor amines' such as adrenaline or other drugs from the same group.
- Oral agents for diabetes or insulins.

Please also inform your doctor if you are taking "*Sortiva H*" and you will be undergoing a radiographic procedure and will be given iodine contrast media.

Taking "*Sortiva H*" with food and drink

You are advised not to drink alcohol whilst taking these tablets: alcohol and "*Sortiva H*" tablets may increase each other's effects.

Dietary salt in excessive quantities may counteract the effect of "*Sortiva H*" tablets.

"*Sortiva H*" tablets 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 H*" before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of "*Sortiva H*". "*Sortiva H*" 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 H*" is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

Use in children and adolescents

There is no experience with the use of "*Sortiva H*" in children. Therefore, "*Sortiva H*" should not be given to children.

Use in elderly patients

"*Sortiva H*" works equally well in and is equally well tolerated by most older and younger adult patients. Most older patients require the same dose as younger patients.

Driving and using machines

When you begin treatment with this medication, you should not perform tasks which may require special attention (for example, driving an automobile or operating dangerous machinery) until you know how you tolerate your medicine.

3. HOW TO TAKE "*Sortiva H*"

Always take "*Sortiva H*" exactly as your doctor has instructed you. Your doctor will decide on the appropriate dose of "*Sortiva H*" depending on your condition and whether you are taking other medicines. It is important to continue taking "*Sortiva H*" for as

long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

High Blood Pressure

The usual dose of "*Sortiva H*" for most patients with high blood pressure is 1 tablet of "*Sortiva H*" 50 mg/12.5 mg per day to control blood pressure over the 24-hour period. This can be increased to 2 tablets once daily of Losartan / Hydrochlorothiazide 50 mg/12.5 mg Film-Coated Tablets or changed to 1 tablet daily of Losartan / Hydrochlorothiazide 100 mg/25 mg Film-Coated Tablets (a stronger strength) per day. The maximum daily dose is 2 tablets per day of Losartan / Hydrochlorothiazide 50 mg/12.5 mg Film-Coated Tablets or 1 tablet daily of Losartan / Hydrochlorothiazide 100 mg/25 mg Film-Coated Tablets.

If you take more "*Sortiva H*" than you should

In case of an overdose, contact your doctor immediately so that medical attention may be given promptly. Overdose can cause a drop in blood pressure, palpitations, slow pulse, changes in blood composition, and dehydration.

If you forget to take "*Sortiva H*"

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, "*Sortiva H*" tablets can cause side effects, although not everybody gets them.

If you experience the following, stop taking "*Sortiva H*" 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 hospitalisation.

The following side effects have been reported:

Common (affecting less than one person in 10 but more than one person in 100):

- Cough, upper airway infection, congestion in the nose, sinusitis, and sinus disorder.
- Diarrhoea, abdominal pain, nausea, indigestion.
- Muscle pain or cramps, leg pain, back pain.
- Insomnia, headache, dizziness.
- Weakness, tiredness, chest pain.
- Increased potassium levels (which can cause an abnormal heart rhythm), decreased haemoglobin levels.
- Changes in kidney function including kidney failure.
- Too low sugar in the blood (hypoglycaemia).

Uncommon (affecting less than one person in 100 but more than one person in 1,000):

- Anaemia, red or brownish spots on the skin (sometimes especially on the feet, legs, arms and buttocks, with joint pain, swelling of the hands and feet and stomach pain), bruising, reduction in white blood cells, clotting problems, reduced number of platelets.
- Loss of appetite, increased uric acid levels or frank gout, increased blood sugar levels, abnormal blood electrolyte levels.
- Anxiety, nervousness, panic disorder (recurring panic attacks), confusion, depression, abnormal dreams, sleep disorders, sleepiness, memory impairment.
- Pins and needles or similar sensations, pain in the extremities, trembling, migraine, fainting.
- Blurred vision, burning or stinging in the eyes, conjunctivitis, worsening eyesight, seeing things in yellow.
- Ringing, buzzing, roaring or clicking in the ears, vertigo. Low blood pressure, which may be associated with changes in posture (feeling light-headed or weak when you stand up, angina (chest pain), abnormal heartbeat, cerebrovascular accident (TIA, "mini-stroke"), heart attack, palpitations
- Inflammation of blood vessels, which is often associated with a skin rash or bruising.
- Sore throat, breathlessness, bronchitis, pneumonia, water on the lungs (which causes difficulty breathing), nosebleed, runny nose, congestion.

- Constipation, obstipation, wind, stomach upsets, stomach spasms, vomiting, dry mouth, inflammation of a salivary gland, toothache.
- Jaundice (yellowing of the eyes and skin), inflammation of the pancreas.
- Hives, itching, inflammation of the skin, rash, redness of the skin, sensitivity to light, dry skin, flushing, sweating, hair loss.
- Pain in the arms, shoulders, hips, knees or other joints, joint swelling, stiffness, muscle weakness.
- Frequent urination including at night, abnormal kidney function including inflammation of the kidneys, urinary tract infection, sugar in the urine.
- Decreased sexual appetite, impotence.
- Swelling of the face, localised swelling (oedema), fever.

Rare (more than 1 out of 10000 patients and less than 1 out of 1000 patients):

Hepatitis (inflammation of the liver), abnormal liver function tests.

Not known

- Flu-like symptoms.
- Unexplained muscle pain with dark (tea-colored) urine (rhabdomyolysis).
- Low levels of sodium in the blood (hyponatraemia).
- Generally feeling unwell (malaise).

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE “Sortiva H”

Keep out of the reach and sight of children.

Do not use “*Sortiva H*” after the expiry date which is stated on the container.

The expiry date refers to the last day of that month.

Store “*Sortiva H*” in the original package in order to protect from light and moisture. Do not store the package above 30°C.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What “Sortiva H” contains

The active substances are losartan potassium and hydrochlorothiazide.

- “*Sortiva H*” 100 mg/12.5 mg contains 100 mg of losartan potassium and 12.5 mg of hydrochlorothiazide as the active ingredients.

- “*Sortiva H*” 100 mg/25 mg contains 100 mg Losartan potassium and 25 mg Hydrochlorothiazide as the active ingredient.

- “*Sortiva H*” 50 mg/12.5 mg contains 50 mg Losartan potassium and 12.5 mg Hydrochlorothiazide as the active ingredient.

“*Sortiva H*” 100 mg/12.5 mg, “*Sortiva H*” 100 mg/25 mg and “*Sortiva H*” 50 mg/12.5 mg contain the following inactive ingredients: Avicel PH 102, croscarmellose Sodium, colloidal silicon dioxide, purified talc, magnesium stearate.

Film-Coating: Polysorbate, titanium dioxide, purified talc, polyethylene glycol, hydroxypropyl methylcellulose, iron oxide red, ariabel yellow.

What *Sortiva H* looks like and contents of the pack

Sortiva H available as film-coated tablets in blister packs of 30 tablets.

Sortiva-H 50/12.5 mg Tablets: Light yellow, round biconvex film-coated tablet engraved with “214” on one side and plain on the other side.

Sortiva-H 100/25 mg Tablets: Light pink, round biconvex film-coated tablet engraved with “203” on one side and plain on the other side.

Sortiva-H 100/12.5 mg Tablets: A light brown color, round, biconvex, film coated tablet engraved with crescent sign on one side and plain on the other side.

This leaflet was last approved in May 2012.