

SARANTO

Losartan Potassium Tablet (50 mg, 100 mg)

Consumer Medication Information Leaflet (RiMUP)

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What is Saranto used for

- Hypertension (High Blood Pressure)
- Hypertensive Patients with Left Ventricular Hypertrophy (Enlargement of Left Ventricle of the Heart).

Losartan Potassium is indicated to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy.

- Nephropathy (Appearance of Low but abnormal levels of albumin in the urine) in Type 2 Diabetic Patients

Losartan Potassium may also be used to treat other conditions, for example, heart failure and kidney disease in diabetic patients with high blood pressure.

How Saranto works

Saranto 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. Saranto prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax which in turn lowers the blood pressure. Saranto slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Before you use Saranto

-When you must not use it

- You are allergic (hypersensitive) to losartan or any of its other ingredients,
- You are more than 3 months pregnant. (It is also better to avoid Saranto in early pregnancy)

-Before you start to use it

It is important to tell your doctor before taking Saranto if :-

- You have a history of angioedema (swelling of the face, lips, throat, mouth and/or tongue) as you may be more likely to develop an allergic reaction.
- You think you are (or might become) pregnant. Saranto 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.
- You suffer from excessive vomiting or diarrhoea leading to an extreme loss of fluid and/or salt in your body.
- You take diuretics (medicines that increase the amount of water that you pass out through your kidneys) or are on a salt restricted diet.
- 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,

-Taking other medications

Take particular care and tell your doctor if you are taking the following medicines while under treatment with Saranto:

- Other drugs that block angiotensin II or its effects, concomitant use of potassium-sparing diuretics (e.g., spironolactone, triamterene, amiloride), potassium supplements, or salt substitutes containing potassium may lead to increases in serum potassium.

- Non-steroidal anti-inflammatory drugs (NSAIDs) including selective cyclooxygenase-2 inhibitors (COX-2 inhibitors) may reduce the effect of diuretics and other antihypertensive drugs. Therefore, the antihypertensive effect of angiotensin II receptor antagonists may be attenuated by NSAIDs including selective COX-2 inhibitors. Using these medicines together may also lead to a worsening in kidney function, especially in people with kidney problems.
- 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.

How to use Saranto

-How much to use

Saranto may be administered with other antihypertensive agents.

Hypertension

The usual starting and maintenance dose is 50 mg once daily for most patients. The maximal antihypertensive effect is attained 3-6 weeks after initiation of therapy. Some patients may receive an additional benefit by increasing the dose to 100 mg once daily.

No initial dosage adjustment is necessary for elderly patients or for patients with kidney problem, including patients on dialysis. A lower dose should be considered for patients with a history of liver problem.

Hypertensive Patients with Left Ventricular Hypertrophy (Enlargement of Left Ventricle of the Heart).

The usual starting dose is 50 mg once daily. Your doctor will adjust your dose and medication based on your blood pressure response.

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Nephropathy (Appearance of Low but abnormal levels of albumin in the urine) in Type 2 Diabetic Patients

The usual starting dose is 50 mg once daily. Your doctor will adjust your dose and medication based on your blood pressure response.

-When to use it

Saranto may be administered with or without food.

-How long to use it

It is important to continue taking Saranto for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

-If you forget to use it

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 product, ask your doctor or pharmacist.

-If you use too much (overdose)

If you accidentally take too many tablets, or a child swallows some, contact your doctor immediately or go to the nearest hospital emergency department. Symptoms of overdose are low blood pressure and changes in the heartbeat (increased heartbeat or possibly decreased heartbeat).

While you are using it

-Things you must do

- Always take Saranto exactly as your doctor has told you.
- Your doctor will decide on the correct dose of Saranto, depending on your condition and whether you are taking other medicines.
- It is important to continue taking Saranto for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure

-Things you must not do

Do not use Saranto after the expiry date which is stated on the carton

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

-Things to be careful of

DO NOT take Saranto if:

- You have a history of angioedema (swelling of the face, lips, throat, mouth and/or tongue) as you may be more likely to develop an allergic reaction.
- You think you are (or might become) pregnant. Saranto 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.
- You suffer from excessive vomiting or diarrhoea leading to an extreme loss of fluid and/or salt in your body.
- You take diuretics (medicines that increase the amount of water that you pass out through your kidneys) or are on a salt restricted diet.
- 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.
- Your liver function is impaired.
- You suffer from heart failure with or without kidney problems or have serious disturbances in your heart rhythm. Special caution is necessary when you are treated with a beta-blocker concomitantly.
- You have problems with your heart valves or heart muscle.
- 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).
- You suffer from primary hyperaldosteronism (a condition associated with increased secretion of the hormone aldosterone by the adrenal gland).

Side effects

Like all medicines, Saranto can cause side effects, although not everybody gets them.

If you experience the following serious side effects, **stop taking Saranto tablets and tell your doctor immediately or go to the casualty department of your nearest hospital. You may need urgent medical attention or hospitalization.**

- A severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing),
- Severe chest pain (angina pectoris),
- Very rapid and irregular heartbeat (atrial fibrillation),
- Stroke.

Other side effects

If you suffer from any of the following side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Common side effects:

- Dizziness or a feeling of spinning,
- Low blood pressure,
- Weakness,
- Tiredness (fatigue),
- Low blood sugar (hypoglycaemia),
- High potassium levels in the blood (hyperkalaemia).

If you suffer from any of the above side effects, or if you notice side effects not listed above then please tell your doctor or pharmacist.

You may report any side effects or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website nppra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety)

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Storage and Disposal of Saranto

-Storage

Store in a dry place below 30° C.
Keep out of the reach and sight of children.

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

This medicinal product does not require any special storage conditions.

-Disposal

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.

Product Description

-What it looks like

Saranto 50 mg tablets:

White to off-white, oval shaped, Biconvex film-coated tablets debossed with 'E' on one side and '4' and '6'' separated by a scoreline on other.

Saranto 100 mg tablets:

White to off-white, oval shaped, biconvex film-coated tablets debossed with 'E' on one side and '47' on other side.

-Ingredients

• Active ingredient(s)

The active substance is losartan potassium.

Each 50 mg film-coated tablet contains 50 mg losartan potassium.

Each 100 mg film-coated tablet contains 100 mg losartan potassium.

• Inactive ingredient(s)

The other ingredients are cellulose microcrystalline, lactose monohydrate, pregelatinised starch (maize), hydroxypropyl cellulose, magnesium stearate, purified water & Opadry white.

-MAL number

Saranto 50 mg: MAL12085064AZ

Saranto 100 mg: MAL14115010AZ

Manufacturer

Aurobindo Pharma Ltd
Unit III, Survey No. 313 & 314,
Bachupally, Bachupally Mandal,
Medchal-Malkajgiri District,
Telangana State, India.

Product Registration Holder

Healol Pharmaceuticals Sdn Bhd
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Date of revision

09/12/2017

Serial Number

NPRA(Rx/x)xxxxxx/xxxxx