

# SARANTO-H

Losartan Potassium and Hydrochlorothiazide (50/12.5 mg)

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## What is SARANTO-H used for

- Hypertension: Saranto-H is indicated for the treatment of hypertension, for patients in whom combination therapy is appropriate.
- Hypertensive Patients with Left Ventricular Hypertrophy: Saranto-H is indicated to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy, but there is evidence that this benefit does not apply to Black patients.

## How SARANTO-H works

Saranto-H is the first combination of an angiotensin II receptor antagonist and a diuretic.

Losartan inhibits systolic and diastolic pressor responses to angiotensin II infusions. At peak, Losartan potassium 100 mg inhibits these responses by approximately 85%; 24 hrs after single and multiple-dose administration, inhibition is about 26-39%.

## Before you use SARANTO-H

### -When you must not use it

#### *In case of*

- Hepatic and Renal Impairment
- Renal Function Impairment:
- Hypotension and Electrolyte/Fluid Imbalance.
- Metabolic and Endocrine Effects.

### -Before you start to use it

*It is important to tell your doctor before taking Saranto-H in case of :-*

- Patients with a history of angiooedema (swelling of the face, lips, throat, and/or tongue) should be closely monitored
- Symptomatic hypotension, especially after the first dose, may occur in patients who are volume-and/or sodium depleted by vigorous diuretic therapy, dietary salt restriction, diarrhoea or vomiting. Such conditions should be corrected before the administration of Saranto-H.
- Electrolyte imbalances are common in patients with renal impairment, with or without diabetes, and should be addressed. Therefore, the plasma concentrations of potassium and creatinine clearance values should be closely monitored; especially patients with heart failure and a creatinine clearance between 30-50 ml/min should be closely monitored.
- Based on pharmacokinetic data which demonstrate significantly increased plasma concentrations of Losartan in cirrhotic patients, Saranto-H should be used with caution in patients with a history of mild to moderate hepatic impairment. There is no therapeutic experience with Losartan in patients with severe hepatic impairment. Therefore Saranto-H is contraindicated in patients with severe hepatic impairment.
- If you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Saranto-H.
- if you experience breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking IRB-H, seek medical attention immediately.

### -Taking other medications

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

- As with other drugs that block angiotensin II or its effects, concomitant use of potassium-sparing diuretics (eg, 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.
- In some patients with compromised renal function who are being treated with nonsteroidal anti-inflammatory drugs, including selective clooxygenase-2 inhibitors, the coadministration of angiotensin II receptor antagonists may result in a further deterioration of renal function. These effects are usually reversible.
- Hydrochlorothiazide: When given concurrently, the following drugs may interact with thiazide diuretics: Alcohol, Barbiturates or Narcotics: Potentiation of orthostatic hypotension may occur.

## How to use SARANTO-H

### -How much to use

Saranto-H may be administered with other antihypertensive agents.

Saranto-H may be administered with or without food. Fixed -dose combinations not indicated for initial therapy.

**Hypertension:** The usual starting and maintenance dose of Saranto-H is 1 tab of Saranto-H 50/12.5 once daily. For patients who do not respond adequately to Losartan Potassium and Hydrochlorothiazide Tablets 50/12.5, the dosage may be increased to 2 tabs of Losartan Potassium and Hydrochlorothiazide Tablets 50/12.5 once daily. The maximum dose is 2

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tabs of Losartan Potassium and Hydrochlorothiazide Tablets 50/12.5 once daily. In general, the antihypertensive effect is attained within 3 weeks after initiation of therapy.

Saranto-H should not be initiated in patients who are intravascularly volume-depleted (eg, those treated with high-dose diuretics).

Saranto-H is not recommended for patients with severe renal impairment (creatinine clearance <30 mL/min) or for patients with hepatic impairment. No initial dosage adjustment of Saranto-H is necessary for elderly patients.

## Hypertensive Patients with Left Ventricular Hypertrophy:

The usual starting dose is Losartan 50 mg once daily. If goal blood pressure is not reached with losartan 50 mg, therapy should be titrated using a combination of losartan and a low dose of hydrochlorothiazide (12.5 mg).

Losartan Potassium and Hydrochlorothiazide Tablets 50/12.5 are suitable alternative formulations in patients who would otherwise be treated concomitantly with losartan plus hydrochlorothiazide.

### -When to use it

Saranto-H may be administered with or without food.

### -How long to use it

It is important to continue taking Saranto-H 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)

No specific information is available on the treatment of overdose with Saranto-H.

Treatment is symptomatic and supportive. Therapy with Saranto-H should be discontinued and the patient observed closely. Suggested measures include induction of emesis if ingestion is recent, and correction of dehydration, electrolyte imbalance, hepatic coma and hypotension by established procedures.

Losartan: The most likely manifestation of over dosage would be hypotension and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation. If symptomatic hypotension should occur, supportive treatment should be instituted.

Neither Losartan nor the active metabolite can be removed by hemodialysis. Hydrochlorothiazide: The most common signs and symptoms observed are those caused by electrolyte depletion (hypokalemia, hypochloremia, hyponatremia) and dehydration resulting from excessive diuresis. If digitalis has also been administered, hypokalemia may accentuate cardiac arrhythmias.

The degree to which hydrochlorothiazide is removed by hemodialysis has not been established.

## While you are using it

### -Things you must do

- Always take Saranto-H exactly as your doctor has told you.
- Your doctor will decide on the correct dose of Saranto-H, depending on your condition and whether you are taking other medicines.
- It is important to continue taking Saranto-H 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-H 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-H if:**

- you are allergic (hypersensitive) to Losartan or any of its other ingredients,
- your liver function is severely impaired,
- you are more than 3 months pregnant.

(It is also better to avoid Losartan Potassium & Hydrochlorothiazide Tablets in early pregnancy.)

#### **Take special care with Saranto-H**

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

- Patients with a history of angioedema (swelling of the face, lips, throat, and/or tongue) should be closely monitored
- Symptomatic hypotension, especially after the first dose, may occur in patients who are volume- and/or sodium- depleted by vigorous diuretic therapy, dietary salt restriction, diarrhoea or vomiting. Such conditions should be corrected before the administration of Saranto-H.
- Electrolyte imbalances are common in patients with renal impairment, with or without diabetes, and should be addressed. Therefore, the plasma concentrations of potassium and creatinine clearance values should be closely monitored; especially patients with heart failure and a creatinine clearance between 30-50 ml/min should be closely monitored.
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## Side effects

The adverse reactions were restricted to those which were formerly observed with Losartan Potassium salt and/ or hydrochlorothiazide.

Next to these effects, there are further adverse reactions reported after the introduction of the product to the market as follows:

### Hepato-biliary disorders

Rare: Hepatitis

### Investigations

Rare: Hyperkalaemia, elevation of ALT

Additional adverse reactions that have been seen with one of the individual components and may be potential adverse reactions with Saranto-H are the following:

## Losartan

Dizziness may occur. In addition, doserelated orthostatic effects may be seen. The most common drug-related side effects were dizziness, asthenia/fatigue and vertigo.

Losartan Potassium was generally well tolerated in type 2 diabetic patients with nephropathy. The most common drug related side effects were asthenia/fatigue, dizziness, hypotension and hyperkalaemia. The following adverse reactions may occur:

**Hypersensitivity:** Anaphylactic reactions, angioedema including swelling of the larynx and glottis causing airway obstruction and/or swelling of the face, lips, pharynx, and/or tongue occur rarely in patients treated with Losartan; some of these patients previously experienced angioedema with other drugs including ACE inhibitors. Vasculitis, including Henoch-Schonlein purpura, may occur rarely.

**Gastro-intestinal:** Hepatitis (rarely), diarrhoea, and liver function abnormalities.

**Haematologic:** Anaemia, thrombocytopenia.

**Musculoskeletal:** Myalgia, arthralgia.

**Nervous system/Psychiatric:** Migraine.

**Respiratory:** Cough.

**Skin:** Urticaria, pruritus, rash.

## Hydrochlorothiazide

### Blood and lymphatic system disorders

Uncommon: Agranulocytosis, aplastic anaemia, haemolytic anaemia, leukopenia, purpura, thrombocytopenia

### Immune system disorders

Rare: Anaphylactic reaction

### Metabolism and nutrition disorders

Uncommon: Anorexia, hyperglycaemia, Hyperuricaemia, hypokalaemia, hyponatraemia

### Psychiatric disorders

Uncommon: Insomnia

### Nervous system disorders

Common: Cephalalgia

### Eye disorders

Uncommon: Transient blurred vision, xanthopsia

### Vascular disorders

Uncommon: Necrotising angitis (vasculitis, cutaneous vasculitis)

### Respiratory, thoracic and mediastinal disorders

Uncommon: Respiratory distress including pneumonitis and pulmonary oedema

Very Rare: Acute respiratory distress (signs include severe shortness of breath, fever, weakness and confusion).

### Gastrointestinal disorders

Uncommon: Sialoadenitis, spasms, stomach irritation, nausea, vomiting, diarrhoea, constipation

### Hepato-biliary disorders

Uncommon: Icterus (intrahepatic cholestasis), pancreatitis

### Skin and subcutaneous tissue disorders

Uncommon: Photosensitivity, urticaria, toxic epidermal necrolysis

### Musculoskeletal and connective tissue disorders

Uncommon: Muscle cramps

### Renal and urinary disorders

Uncommon: Glycosuria, interstitial nephritis, renal dysfunction, renal failure

### General disorders and administration site conditions

Uncommon: Fever, dizziness.

Frequency 'not known': Skin and lip cancer (Non-melanoma skin cancer).

Frequency 'not known':

- Choroidal effusion: an abnormal building of liquid in your eye that may result in vision changes;
- Acute myopia: sudden nearsightedness or blurred vision;
- Acute angle-closure glaucoma: a rapid increased pressure in your eyes, eye pain. If left untreated, it may lead to permanent vision loss.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## Storage and Disposal of SARANTO-H

### -Storage

Do not store above 30°C.

### -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-H 50/12.5 mg film-coated tablets:**

Yellow coloured, oval shaped, beveled edge, biconvex film-coated tablets debossed with 'E' on one side and '48' on the other side.

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## -Ingredients

- Active ingredient(s)  
The active substance is Losartan potassium & Hydrochlorothiazide. Each 50/12.5 mg film-coated tablet contains 50 mg Losartan potassium and 12.5 mg of Hydrochlorothiazide.
- Inactive ingredient(s)  
The other ingredients are cellulose microcrystalline, lactose monohydrate, pregelatinised starch (maize), hydroxypropyl cellulose, magnesium stearate & Opadry Yellow.

## -MAL number

MAL16075019AZ

## **Manufacturer**

Aurobindo Pharma Limited, Unit-III,  
Survey No. 313 & 314,  
Bachupally, Bachupally Mandal,  
Medchal-Malkajgiri District,  
Telangana State, India.  
Regd. Office: Plot No.: 2, Maitrivihar,  
Ameerpet, Hyderabad-500 038,  
Telangana State, India.

## **Product Registration Holder**

Healol Pharmaceuticals Sdn. Bhd.,  
74-3, Jalan Wangsa Delima 6, KLSC  
Wangsa Maju, 53300 Kuala Lumpur,  
Malaysia.

## **Date of revision**

-11/10/2024

## **Serial Number**

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