

Hartan 50mg film-coated tablets

Consumer Medication Information Leaflet
(RiMUP)

Active ingredient: Losartan potassium 50 mg

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What Hartan 50mg film-coated tablets is used for

- Treat hypertension (high blood pressure).
- Reduce the risk of stroke (a sudden attack of weakness affecting one side of the body) in patients with high blood pressure and left ventricular hypertrophy (a thickening of the left ventricle of the heart).
- To slow the worsening of diabetic kidney disease (nephropathy) in the patients with type 2 diabetes who have or had high blood pressure.

How Hartan 50mg film-coated tablets works

Losartan belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin II is a chemical in your body, which tightens your blood vessels making it harder for the blood to pass through them and causes your blood pressure to increase.

Losartan blocks this effect, causing the blood vessels to relax and so lowers your blood pressure.

Before you use Hartan 50mg film-coated tablets

- When you must not use it

- You are allergic to losartan potassium or any of the other ingredients of this drug.
 - You are more than 3 months pregnant.
- If you think any of these apply to you, or if you are in any doubt at all, consult your doctor before taking this drug.*

- Before you start to use it

If any of the situations mentioned below apply to you, you should tell your doctor before taking this drug:

- If you have renal artery stenosis

- (narrowing of the kidney artery).
- If you have kidney or liver dysfunction.
- If you have volume depletion (a reduction in extracellular fluid volume).
- If you think you are (or might become) pregnant.
- If you are in breast-feeding.

- Taking other medicines

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

Some other medicines may influence the use of this drug or vice versa.

You should specifically tell your doctor if you are taking:

- Rifampicin (an antibiotic drug).
- Fluconazole (used for treatment of fungal infections).
- Potassium-sparing diuretics (e.g., spironolactone, triamterene, amiloride), potassium supplements, potassium-containing salt substitutes.
- Medicines used to treat pain and arthritis, called non-steroid anti-inflammatory drugs (NSAIDs).

How to use Hartan 50mg film-coated tablets

- How much to use

Always take this drug exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- High blood pressure:
Adult: The usual dose is 50 mg once daily. The dose may be increased, if necessary, to 100 mg daily as a single dose or in two divided doses. The maximum hypotensive (lower blood pressure) effect is achieved in about 3 to 6 weeks after initiating treatment.
For patients with intravascular volume-depletion (e.g., those treated with high-dose diuretics), a starting dose of 25 mg once daily should be considered.
No initial dosage adjustment is necessary for elderly patients or for patients with kidney failure, including patients on dialysis (a process for removing waste and excess water from the blood, and is used primarily as an artificial replacement for lost kidney function in people with renal failure).
A lower dose should be considered for patients with a history of liver failure.
- High blood pressure and a thickening of

the left ventricle of the heart:

The usual starting dose is 50 mg once daily. A low dose of hydrochlorothiazide should be added and/or the dose of Hartan 50mg film-coated tablets should be increased to 100 mg once daily based on blood pressure response.

- Kidney protection in type 2 diabetes patients with proteinuria (presence of protein in urine) and high blood pressure: The usual starting dose is 50 mg once daily. The dose may be increased to 100 mg once daily based on blood pressure response. Hartan 50mg film-coated tablets may be administered with other antihypertensive agents (e.g. diuretic, calcium channel blockers, α - or β -blockers and centrally acting agents) as well as with insulin and other commonly used hypoglycemic agents (e.g. sulfonylureas, glitazones and glucosidase inhibitors).

- When to use it

Losartan tablet can be taken with or without food.

You should take your medicine regularly and at the same time each day.

- How long to use it

You should take this drug for as long as your doctor continues to prescribe it.

- If you forget to use it

If you miss a dose, take it as soon as you remember. If it is close to your next dose, do not take the missed dose. Just take the next dose at your regular time.

- If you use too much (overdose)

If you take too much Losartan tablet, call your doctor or poison control center, or go to the nearest hospital emergency room right now.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

While you are using it

- Things you must do

You should have serum-potassium concentration monitored especially in the elderly and patients with kidney dysfunction.

- Things you must not do

Do not stop the treatment. Contact your doctor or pharmacist before stopping.

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- Things to be careful of

Do not take this drug if you think you are (or might become) pregnant. Losartan tablet 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.

Side effects

Like all medicines, Hartan 50mg film-coated tablets can cause side effects, although not everybody gets them.

- Dizziness, headache and dose-related orthostatic hypotension (A fall in blood pressure on standing up which causes dizziness, light-headedness or fainting).
- Low blood pressure.
- Kidney failure.
- High levels of blood potassium which can cause abnormal heart rhythm (hyperkalaemia), muscle pain (myalgia), joint pain (arthralgia).
- Cough.
- Respiratory-tract disorders, back pain, stomach or intestinal disorder fatigue, decrease in the number of neutrophils in the blood (neutropenia).

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

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 [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Hartan 50mg film-coated tablets

Storage

The expiry date of this pack is printed on the box. Do not use this pack after this date.

Protect from light. Do not store above 30°C.

Keep all medicines out of reach of children.

- 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

Hartan 50mg film-coated tablets appears as a white, round-shaped, film-coated tablet, biconvex, quadrisectioned on both sides.

- Ingredients

Active ingredient: One tablet contains 50 mg of losartan potassium.

Inactive ingredients: Lactose monohydrate, starch pregelatinized, microcrystalline cellulose, colloidal silicon dioxide, magnesium stearate, hypromellose, macrogol 400, talc, titanium dioxide, carnauba wax.

- MAL number:

MAL14055015AZ

Manufacturer:

STELLAPHARM J.V. CO., LTD. – BRANCH 1 (A Joint Venture Company of Auxilto GmbH, Germany)

No. 40 Tu Do Avenue, Vietnam - Singapore Industrial Park, An Phu Ward, Thuan An Town, Binh Duong Province, Vietnam.

Product Registration Holder

STADPHARM SDN. BHD.
E-9-01, Oasis Square, Ara Damansara
No: 2, Jalan PJU 1A/7A, 47301 Petaling Jaya, Selangor Darul Ehsan, Malaysia.

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