TOSAN TABLET 50MG

Losartan Potassium 50mg

Consumer Medication Information Leaflet (RiMUP)

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Read this entire leaflet before you start taking the medication.

- Keep this leaflet. You may need to read again.
- Ask your doctor or pharmacist if you need more information or advice.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

WHAT TOSAN IS USED FOR

Tosan contains the active ingredient Losartan potassium.

Tosan is used to treat:

- High blood pressure (hypertension).
- High blood pressure with thickening of the left ventricle, which Tosan is shown to reduce the risk of stroke
- Protect the kidney in diabetic patients with evidence of impaired kidney function.

HOW TOSAN WORKS

Losartan belongs to the group of medicines called angiotensin-II receptors antagonist. Angiotensin-II is a substance produce in the body which binds to the receptors in the blood vessels, causing them to tighten. This results in increase in blood pressure.

Losartan works by preventing Angiotensin-II from binding to these receptors, resulting in relaxation of the blood vessels and in turn lowers the blood pressure. Losartan slows

the decrease of kidney function in patient with high blood pressure and type 2 diabetes.

BEFORE YOU USE TOSAN

When you must not use it

Do not take Tosan if you:

- Are pregnant, or think you are pregnant.
- Have ever had allergic reaction to losartan, the active ingredient, or to any other ingredients in Tosan,

If you are not sure whether you should start taking this medicine, consult your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you:

- Think you are (or might become) pregnant,
- Have a history of swelling of the face, lips, tongue, throat, hands or feet.
- Recently suffered from excessive vomiting or diarrhea leading to extreme loss of fluid and/or salt in your body,
- Receive diuretics (medicines that increase urine output) or are under dietary salt restriction leading to extreme loss of fluid and/or salt in your body,
- Suffer from any kidney problems,
- Suffer from any liver problems,
- Suffer from diabetes,
- Suffer from heart disease, in particular problems with the muscles or valves of the heart,

Taking other medicines

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

Some medicines and Tosan may interfere with each other. It is important to tell your doctor or pharmacist if you are taking:

- Medicines which retain potassium or may increase potassium levels (e.g. potassium supplements, salts substitute containing potassium or potassium-sparing diuretic such as spironolactone and amiloride),
- Diuretics tablet, such as frusemide,

- Non-steroidal anti-inflammatory drugs (NSAIDS) (e.g. indomethacin), including COX-2 inhibitors (e.g. celecoxib), for pain relief and reduce inflammation.
- Lithium containing medicines for mental problem including depression.

Pregnancy and lactation

Tell your doctor if you are pregnant; think you are pregnant or planning to become pregnant. Tosan is not recommended during pregnancy and may caused harm to the baby.

Tell your doctor if you are breastfeeding or about to start breastfeeding. Tosan is not recommended for mothers who are breastfeeding. Your doctor may choose another treatment for you if you wish to breastfeed.

HOW TO USE TOSAN

Always take Tosan exactly according to the instructions given to you by your doctor or pharmacists. If you are unsure, check with your doctor or pharmacist.

How much to use

The dose given by your doctor may differ from this leaflet.

Usual Dosage:

Treatment of high blood pressure:
The treatment usually starts with 50mg (1 tablet) once a day. The maximal blood pressure lowering effect is reached 3 - 6 weeks after initiation of therapy. Some patients may require a higher dose of up to 100mg (2 tablets) once a day

Treatment of high blood pressure in patient with thickening of left ventricle:
The treatment usually starts with 50mg (1 tablet) once a day. A low dose of hydrochlorothiazide (a diuretics) may be added and/or the dose of Tosan may be increased to 100mg (2 tablets) once daily based on your blood pressure response.

Treatment of high blood pressure in diabetic patient with kidney disease:

The treatment usually starts with 50mg (1 tablet) once a day. The dose may be increased to 100mg (2 tablets) once daily depending on your blood pressure response.

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Tosan tablets may be given together 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 or with other commonly used medicines to decrease glucose level in the blood (e.g. sulfonylureas, glitazones and glucosidase inhibitors).

When to use it

Take Tosan at the same time everyday to ensure good control on your blood pressure.

Taking Tosan with food and drink

Tosan can be taken with or without food.

How long to use it

Continue to take your medicines as long as your doctor tells you. This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to use it

Take your dose as soon as you remember and continue to take it as you would normally. Do not take a double dose to make up for the dose you missed.

If you use too much (overdose)

If you or anyone else takes too many tablets, you should immediately go to your nearest hospital emergency department or tell your doctor. Do this even if there are no signs of discomfort or poisoning. Take the carton or any remaining tablets you have with you.

Symptoms of an overdose may include low blood pressure, increased heartbeat, or possibly decreased heartbeat.

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

- Always take Tosan exactly according to the instructions given to you by your doctor or pharmacists. If you are unsure, check with your doctor or pharmacist.
- Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines

- obtained without a prescription such as supplements or traditional medicines.
- Tell your doctor or pharmacist immediately if you notice any side effects, or if the side effects gets serious or anything else that make you feel unwell.
- If you become pregnant, or plan on becoming pregnant while taking Tosan, tell your doctor immediately.
- Tell your doctor if you have excessive vomiting and/or diarrhea.
- If you are about to be started on a new medicine, remind your doctor and pharmacist that you are taking Tosan.

Things you must not do

- Do not stop taking your medicines without consulting your doctor. It is important to keep taking your medicine even if you feel well.
- Do not use Tosan after the expiry date which is stated on the carton and blister.
- Do not give this medication to anyone else, even if they have the same condition as you.

Things to be careful of

• Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. Tosan is unlikely to affect your ability to drive or use machines. However, as with many others medicines used to treat high blood pressure, Tosan may cause dizziness or drowsiness in some people. If you experience dizziness or drowsiness, consult your doctor before attempting such activities.

SIDE EFFECTS

All medicines can have side effects. Tosan may cause unwanted side effects although not everybody gets them.

Tell your doctor or pharmacist if you notice the following *common* side effects:

- Light-headedness or dizziness
- Low blood pressure
- Tiredness or fatigue
- Feeling weak
- Too little sugar in the blood (hypoglycemia), which may be indicated with symptoms such as intense hunger,

- nervousness, sweating, trembling, palpitation or difficulty in speaking.
- Too much potassium in the blood (hyperkalemia), which may be indicated with symptoms such as nausea, fatigue, muscle weakness or tingling sensation,
- Changes in kidney function including kidney failure,
- Signs of anemia such as tiredness, shortness of breath, and looking pale,

The following are *serious but rare* side effects. You may need urgent medical attention.

- Severe allergic reaction (rash, itching, swelling of hands, face, lips or tongue),
- Fainting
- Reduced number of thrombocytes (thrombocytopenia),
- Numbness or tingling sensation (paresthesia),
- Unexplained muscle pain with dark urine (rhabdomyolysis),
- Inflammation of liver (hepatitis),
- Liver function abnormalities.

Tell your doctor or pharmacist immediately if you notice the side effects gets serious or anything else that make you feel unwell.

Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel:03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

STORAGE AND DISPOSAL OF TOSAN Storage

Do not store above 30°C. Store in original package to protect from light and moisture.

Do not store Tosan or any other medicines in the bathroom, near a sink or leave it at the window sill or in the car.

Keep out of the reach and sight of children.

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Disposal

The expiry date of Tosan is printed on the carton and blister. Do not use if after expiry date.

If your doctors tell you to stop taking Tosan or the expiry date has passed, ask your pharmacist what to do with the remaining medicines.

PRODUCT DESCRIPTION

What it looks like

Tosan Tablet is a white oval, biconvex tablet embossed with the letter 'C', 'L' and breakline on one side and figure '50' on the other side.

Tosan comes in the strength of 50mg in blister packs of 30, 50, 100 or 500 tablets per box. Tosan also available in bottle pack of 30 tablets

Active Ingredients

Each Tosan Tablet contains Losartan potassium 50mg.

Inactive Ingredient

Lactose, colloidal silicon dioxide, sodium starch glycolate, microcrystalline cellulose, starch, magnesium stearate, hydroxylpropryl cellulose, hydroxypropyl methylcellulose, titanium dioxide, polyethylene glycol.

Registration Number

MAL11060013A

MANUFACTURER AND PRODUCT REGISTRATION HOLDER

MANUFACTURER

T.O. Chemicals (1979) Co. Ltd. 280 Soi Sabaijai, Suthisarn Road., 10320 Bangkok, Thailand.

PRODUCT REGISTRATION HOLDER

IMEKS Pharma Sdn. Bhd. No. 5 & 9, Jalan Udang Harimau 2, Medan Niaga Kepong, 51200 Kuala Lumpur. Malaysia

Date of Revision: 2-Dec-2013