

New Zealand Consumer Medicine Information

# Losartan HCTad<sup>®</sup> 50mg/12.5mg

## *Losartan potassium/Hydrochlorothiazide*

50 mg/12.5 mg Film-coated tablets

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## What is in this leaflet

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Please read this leaflet carefully before you start taking Losartan HCTad.

This leaflet answers some common questions about Losartan HCTad. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Losartan HCTad against the benefits this medicine is expected to have for you.

**If you have any concerns about taking Losartan HCTad, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may want to read it again.

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## What Losartan HCTad is used for

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Losartan HCTad lowers high blood pressure, which doctors call hypertension. It may be used alone or in combination with other medicines. In patients with high blood pressure and a thickening of the left ventricle, losartan, often in combination with hydrochlorothiazide, reduces the risk of stroke and heart attack and helps patients live longer.

Everyone has blood pressure. This pressure helps get your blood all around your body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed. Over time, high blood pressure causes the heart to work harder, which can lead to a thickening of the left ventricle. A thickening of the left ventricle of the heart is associated with an increased chance of experiencing a stroke.

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems, including stroke, heart disease or kidney failure.

Losartan HCTad contains two active ingredients, losartan potassium and hydrochlorothiazide. They work together to lower high blood pressure. Losartan potassium belongs to a group of medicines called angiotensin II receptor antagonists and lowers blood pressure by relaxing your blood vessels. Hydrochlorothiazide is a fluid tablet or diuretic and lowers blood pressure by reducing the amount of excess fluid in the body by increasing the amount of urine produced.

Your doctor may have prescribed Losartan HCTad for another reason.

**Ask your doctor if you have any questions about why Losartan HCTad has been prescribed for you.**

This medication is only available with a doctor's prescription.

Losartan HCTad is not addictive.

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## Before you take Losartan HCTad

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Losartan HCTad is not suitable for everyone.

### ***When you must not take it***

#### **Do not take Losartan HCTad if you:**

- are allergic to losartan potassium, hydrochlorothiazide, or any of the ingredients listed at the end of this leaflet
- are allergic to any sulphonamide or sulphur medicines.  
Losartan HCTad contains hydrochlorothiazide, a sulphur-containing medicine (sulphonamide). Therefore, if you are allergic to sulphur medicines, such as some antibiotics, you are likely to be allergic to Losartan HCTad.
- you are not passing urine
- you are pregnant or breast-feeding.  
Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.

**Do not take it after the expiry date ('Exp. date') printed on the pack.**  
If you take it after the expiry date has passed, it may not work as well.

**Do not take it if the packaging is torn or shows signs of tampering.**

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

### ***Before you start to take it***

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

**Tell your doctor or pharmacist if you have or have had any of the following medical conditions:**

- a history of angiooedema (swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing)
- liver or kidney problems
- hyperaldosteronism, a medical condition where too much aldosterone is produced by the adrenal glands, which can lead to lowered levels of potassium in the blood
- heart problems or heart failure
- diseases related to reduced blood flow in the blood vessels of the heart muscle or the brain (cardiovascular or cerebrovascular diseases)
- diabetes
- gout
- systemic lupus erythematosus (known as SLE), a disease affecting the skin, joints and kidneys
- high cholesterol or triglyceride levels.

**Also tell your doctor if you have recently had excessive vomiting or diarrhoea or if you are following a very low salt diet.**

**Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.**

Losartan HCTad is not recommended for use during pregnancy or while breast-feeding. Your baby may absorb this medicine in the womb and therefore there is a possibility of harm to the baby. It is not known whether the active ingredients in Losartan HCTad pass into breast milk.

**Do not give Losartan HCTad to a child or adolescent.**

There is no experience with its use in children or adolescents under 18 years old.

**If you have not told your doctor or pharmacist about any of the above, tell them before you take Losartan HCTad.**

### ***Taking other medicines***

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. Tell any health professional who is prescribing a new medicine for you that you are taking Losartan HCTad.**

Some medicines and Losartan HCTad may interfere with each other. These include:

- diuretic tablets, also called fluid or water tablets, including potassium-sparing diuretics
- potassium tablets
- potassium-containing salt substitutes
- tricyclic antidepressants, a group of medicines used to treat depression
- antipsychotics (medicines used to treat certain mental and emotional conditions)
- other medicines used to treat high blood pressure
- digoxin, used to treat heart failure
- medicines used to treat irregular heartbeat

- lithium, used to treat severe mood swings and some types of depression
- steroid medicines such as cortisone, prednisone
- glycyrrhizin, found in liquorice root
- insulin and oral medicines used to treat diabetes, including metformin
- barbiturates, used to treat epilepsy, such as phenobarbitone
- strong pain killers such as codeine, morphine, dextropropoxyphene
- non-steroidal anti-inflammatory medicines (NSAIDs) used to treat inflammation, pain, arthritis
- cholestyramine and colestipol, used to treat high cholesterol
- medicines used to relax muscles before and during surgery as well as baclofen, a different type of muscle relaxant
- medicines used in emergency situations such as adrenaline
- medicines used to treat gout, such as probenecid, sulfinpyrazone, allopurinol
- anticholinergic medicines, used to relieve stomach cramps or spasms, to prevent travel sickness and to treat Parkinson's disease (for example, atropine, biperiden)
- medicines used to treat cancer, for example cyclophosphamide, methotrexate
- cyclosporine, used to suppress the immune system
- any medicines containing amifostine, salicylates, bepridil, cisapride, diphemanil, erythromycin IV, halofantrine, mizolastine, pentamidine, terfenadine, vincamine IV
- alcohol.

The above medicines may be affected by Losartan HCTad, or may affect how well it works. You may need different amounts of your medicine, or take it at different times, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Losartan HCTad.

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## How to take Losartan HCTad

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**Read the label carefully and follow all directions given to you by your doctor and pharmacist.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on then pack, ask your doctor or pharmacist for help.**

### ***How much to take***

For most patients, the usual dose is one tablet of Losartan HCTad 50mg/12.5mg once a day. Depending on your condition, the dose may need to be increased to two tablets of Losartan HCTad 50mg/12.5mg once a day.

Your doctor may have prescribed a different dose.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

They will tell you exactly how much to take.

If you take the wrong dose, Losartan HCTad may not work as well and your problem may not improve.

### ***How to take it***

**Swallow Losartan HCTad with a full glass of water.**

### ***When to take it***

**Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take the tablets.

**Take Losartan HCTad before or after food.**

It does not matter whether you take Losartan HCTad before or after food.

### ***How long to take it***

**Continue taking Losartan HCTad for as long as your doctor tells you to.**

Losartan HCTad helps control your high blood pressure but does not cure it. Therefore it must be taken every day.

### ***If you forget to take it***

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not try to make up for missed doses by taking more than one dose at a time.**

This may increase the change of getting an unwanted side effect.

**If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.**

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

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## **While you are taking Losartan HCTad**

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### ***Things you must do***

**If you become pregnant while taking Losartan HCTad, tell your doctor immediately.**

Your doctor needs to know immediately so that Losartan HCTad can be replaced by another medicine.

**If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Losartan HCTad. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are taking this medicine.**

**Have your blood pressure checked when your doctor says, to make sure Losartan HCTad is working.**

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.**

**If you have excessive vomiting and/or diarrhoea while taking Losartan HCTad, or you have any of the following symptoms, tell your doctor:**

- dry mouth, thirst
- weakness, tiredness, drowsiness
- muscle pains or cramps
- fast heart beat
- passing less urine than normal.

You may be dehydrated because you are losing too much water and your blood pressure may become too low.

**If you are going to have surgery (even at the dentist) that needs a general anaesthetic, tell the surgeon, anaesthetist, or dentist that you are taking this medicine.**

**Continue taking potassium tablets if your doctor has prescribed these for you.**

Losartan HCTad contains a very small amount of potassium, but this does not replace any potassium tablets that you may be taking.

### ***Things you must not do***

**Do not give your medicine to anyone else, even if they have the same condition as you.**

This medicine is only intended for the use of the patient it has been prescribed for.

**Do not take Losartan HCTad to treat any other complaints unless your doctor tells you to.**

**Do not stop taking Losartan HCTad or change the dosage without checking with your doctor.**

### ***Things to be careful of***

**If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.**

You may feel light-headed or dizzy when you begin to take Losartan HCTad. This is because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. The problem usually goes away after a few days.

**If this problem gets worse or continues, talk to your doctor.**

**Make sure you drink enough water during exercise and hot weather, especially if you sweat a lot.**

If you do not drink enough water while taking Losartan HCTad, you may faint or feel light-headed or sick. This is because your body doesn't have enough fluid and your blood pressure is low.

**If you continue to feel unwell, tell your doctor.**

**Be careful driving or operating machinery until you know how Losartan HCTad affects you.**

It may cause dizziness or light-headedness in some people especially after the first few doses or if the dose is increased. Make sure you know how you react to Losartan HCTad before you drive a car, operate machinery, or do anything else that could be dangerous. If you drink alcohol, or take strong pain killers or barbiturates, the effects may be worse.

***Things that may help your condition***

Some self help measures suggested below may help lower your blood pressure.

**Talk to your doctor or pharmacist about them:**

- **Alcohol**  
Your doctor may advise you to limit your alcohol intake.
- **Diet**  
Eat a healthy diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar.
- **Exercise**  
Regular exercise helps reduce blood pressure and helps the heart get fitter, but it is important not to overdo it. Walking is good exercise, but try to find a route that is fairly flat. Before starting any exercise, ask your doctor about the best kind of programme for you.
- **Salt**  
Your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake you should avoid using salt in cooking or at the table.
- **Smoking**  
Your doctor may advise you to stop smoking or at least cut down.

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## **In case of overdose**

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***If you take too much (overdose)***

**Immediately telephone your doctor, or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Losartan HCTad.**

**Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

If you take too many tablets, you will probably feel light-headed or dizzy, or you may faint. You may also become very thirsty, confused, have a change in the amount of urine passed or have a fast or irregular heart beat.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Losartan HCTad.**

It helps most people with high blood pressure, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following and they worry you:**

- dizziness/light-headedness
- nausea, vomiting, loss of appetite
- diarrhoea, stomach cramps, constipation
- headache
- dry cough
- weakness, fatigue
- taste alteration
- transient blurred vision or yellow vision
- increased sensitivity of the skin to sun
- generally feeling unwell
- rash, dermatitis
- inability to get or maintain an erection.

These are usually mild side effects of Losartan HCTad, but may be serious.

**Tell your doctor immediately if you notice any of the following:**

- muscle cramps
- severe dizziness, spinning sensation
- fainting
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bruising or bleeding more easily than normal, nose bleeds
- tiredness, headaches, being short of breath when exercising, looking pale
- yellowing of the skin and/or eyes, also called jaundice
- numbness or tingling in the hands or feet
- skin rash, itchiness
- dark coloured urine
- aching muscles, muscle tenderness or weakness, not caused by exercise.

These may be serious side effects. You may need urgent medical attention.

**If any of the following happen, tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:**

- swelling of the face, lips, mouth, or throat which may cause difficulty in swallowing or breathing
- shortness of breath
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash
- severe skin reaction which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Losartan HCTad. You may need urgent medical attention or hospitalisation. These side effects are very rare.

**Tell your doctor if you notice anything else that is making you feel unwell.**

Other adverse effects not listed above may also occur in some patients.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

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## **After taking Losartan HCTad**

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### ***Storage***

**Keep your tablets in the blister pack until it is time to take them.**

If you take the tablets out of the blister pack they may not keep well.

**Keep Losartan HCTad in a cool dry place where the temperature stays below 30°C.**

**Do not store it or any other medicine in the bathroom, near a sink, or on a window sill.**

**Do not leave it in the car.**

Heat and dampness can destroy some medicines.

**Keep it and any other medicine where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Do not keep Losartan HCTad past its expiry date.**

### ***Disposal***

**Return any unused medicine, and any medicine past its expiry date (as shown on the dispensing label or on the packaging) to your pharmacy.**

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## Product description

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### *What it looks like*

Losartan HCTad is available in blisters packs of 98 tablets. The tablets are yellow, oval, film-coated tablets.

### *Ingredients*

This medicine contains lactose.

#### Active ingredient:

- losartan potassium 50mg and hydrochlorothiazide 12.5mg per tablet

#### Inactive ingredients:

- starch – pregelatinised
- cellulose – microcrystalline
- **lactose monohydrate**
- magnesium stearate
- hypromellose
- macrogol 4000
- quinoline yellow
- titanium dioxide
- talc - purified.

Losartan HCTad does not contain sucrose, tartrazine or any other azo dyes.

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## Sponsor details

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Losartan HCTad is supplied in New Zealand by:  
Boucher & Muir (New Zealand) Ltd, trading as BNM Group  
39 Anzac Road  
Browns Bay  
Auckland 0753

Ph: 0800 565 633

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## Date of preparation

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This leaflet was prepared on 18 July 2011.