Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to other people. 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.

The full name of this medicine is Losartan potassium/Hydrochlorothiazide 50/12.5mg and 100/25mg Tablets but within the leaflet it will be referred to as Losartan HCT tablets.

In this leaflet:

1. What Losartan HCT tablets are and what they are used for
2. Before you take
3. How to take
4. Possible side effects
5. How to store
6. Further information

1. What Losartan HCT tablets are and what they are used for

Losartan HCT tablets are a combination of an angiotensin II receptor antagonist (Losartan) and a diuretic (Hydrochlorothiazide).

Losartan HCT Tablets are indicated for the treatment of essential hypertension (high blood pressure).

2. Before you take

Do not take Losartan HCT tablets if you

- have a severe allergy (hypersensitivity) to Losartan, Hydrochlorothiazide, or to any of the other ingredients of Losartan HCT Tablets (see section 6 “What Losartan HCT tablets contain?”)
- are allergic (hypersensitive) to other sulfonamide-derived diuretics (e.g. other thiazides, some antibacterial drugs such as co-trimoxazole, ask your doctor if you are not sure)
- have severely impaired liver function
- are more than 3 months pregnant (it is also better to avoid Losartan HCT Tablets in early pregnancy – see pregnancy section)
- have had a kidney transplant or your kidneys are not producing any urine
- have low potassium, low sodium or high calcium levels which cannot be corrected by treatment
- are suffering from hypoglycaemia

Take special care with Losartan HCT tablets if you

- have previously suffered from swelling of the face, lips, throat or tongue
- take diuretics (water pill)
- are on a salt-restricted diet
- have or have had severe vomiting and/or diarrhoea
- have heart failure
- have narrow arteries to your kidneys (renal artery stenosis) or only have one functioning kidney, or you have recently had a kidney transplant
- have a high level of glucose (hyperglycaemia), or urine ketones (shortage of energy) due to poor heart function
- have ovot or mirror valvular stenosis (narrowing of the valves of the heart) or hypertrophic cardiomyopathy (a disease causing thickening of heart muscle)
- are diabetic
- have had a recent heart attack
- have had an allergic condition, asthma or a condition that causes joint pain, skin rashes and fever (systemic lupus erythematosus)
- have high calcium or low potassium levels or you are on a low potassium diet

- need to have an anaesthetic (even at the dentist) or before surgery, or if you are going to have tests to check your parathyroid function, you must tell the doctor or medical staff that you are taking Losartan HCT tablets.
- suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal glands, caused by an abnormality within the gland).

You must tell your doctor if you think you are or might become pregnant. Losartan HCT tablets are 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 (see pregnancy section).

Taking other medicines

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

Diuretic agents such as the hydrochlorothiazide contained in Losartan HCT Tablets may interact with other medicines.

Preparations containing lithium should not be taken with Losartan HCT tablets without close supervision by your doctor.

Special precautionary measures (e.g. blood tests) may be appropriate if you take lithium preparations, potassium-containing salt substitutes or potassium-sparing medicines, other diuretics (“water tablets”), some laxatives, glycyrrhizin (found in liquorice), medicines for the treatment of gout, medicines to control heart rhythm or for diabetes (oral agents or insulin).

It is also important for your doctor to know if you are taking:

- other medicines to reduce your blood pressure, such as diuretics,
- medicines to treat cancer, such as chemotherapy,
- pain killers,
- drugs for treatment of fungal infections,
- arthritis medicines,
- reis used for high cholesterol, such as colestatemog, medicines which relax your muscles, sleeping tablets,
- opoid medicines such as morphine,
- “pressor amines” such as adrenaline (epinephrine) or other drugs from the same group.

Please also inform your doctor you are taking Losartan HCT tablets if you will be undergoing a radiographic procedure and will be given iodine contrast media.

Taking Losartan HCT tablets with food and drink

You are advised not to drink alcohol whilst taking these tablets: alcohol and Losartan HCT tablets may increase each other's effects.

Dietary salt in excessive quantities may counteract the effect of Losartan HCT Tablets.

Losartan HCT tablets may be taken with or without food.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicines.

Pregnancy

You must tell your doctor if you think you are or might become pregnant. Your doctor will normally advise you to stop taking Losartan HCT tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Losartan HCT tablets. Losartan HCT Tablets are not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breastfeeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Losartan HCT tablets are not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast feed, especially if your baby is newborn, or was born prematurely.

Use in children and adolescents

There is no experience with the use of Losartan HCT tablets in children. Therefore, Losartan HCT tablets should not be given to children.

Continued top of next column

Losartan potassium/Hydrochlorothiazide Film-coated Tablets 50mg/12.5mg, 100mg/25mg PIL

Losartan HCT tablets are indicated for the treatment of essential hypertension (high blood pressure).

Losartan potassium/Hydrochlorothiazide 50/12.5mg and 100/25mg Tablets

-tablet:

item no: L0066ACT-30

print proof no: 2

revised by: M

date sent: 20.05.11

min pt size: 8pt

date received: 6/10/11

origination date: 21.06.11

supplier: Actavis Iceland

actavis

044 1277 3189

044 1277 3164

info@actaviscork.com

mock up only

5A

SA

Technical Approval

date sent: 20.05.11

technical app date: 21/06/11

Non Printing Colours

min pt size: 8pt
Non Printing Colours

Use in elderly patients
Losartan HCT tablets work equally well in and is equally well tolerated by most elderly and younger adult patients. Most older patients require the same dose as younger patients.

Driving and using machines
When you begin treatment with this medication, you should not perform tasks which may require special attention (for example, driving a car or operating dangerous machinery) until you know how you tolerate your medicine.

How to take
Always take Losartan HCT tablets exactly as your doctor has instructed. This is to ensure that you take the appropriate dose of Losartan HCT tablets depending on your condition and on whether you are following other medicines. It is important to continue taking Losartan HCT tablets for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

High blood pressure
The usual dose of Losartan HCT tablets for most patients with high blood pressure is 1 Losartan HCT 50/12.5mg tablet once daily to control blood pressure over the 24-hour period. This can be increased to 2 Losartan HCT 50/12.5mg tablets once daily or 1 Losartan HCT 100/25mg tablet (a stronger strength) once daily. The maximum daily dose is 2 Losartan HCT 50/12.5mg tablets or 1 Losartan HCT 100/25mg tablet.

If you take more Losartan HCT tablets than you should
In case of an overdose, contact your doctor immediately so that medical attention may be given promptly. An overdose can cause a drop in blood pressure, palpitations, slow pulse, changes in blood composition and dehydration.

If you forget to take Losartan HCT Tablets
Try to take Losartan HCT tablets daily as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule.

If you stop taking Losartan HCT Tablets
If you have any further questions on the use of this product, ask your doctor or pharmacist.

Possible side effects
Like all medicines, Losartan HCT tablets can cause side effects, although not everybody gets them.

If you experience the following, stop taking Losartan HCT Tablets and tell your doctor immediately or go to the casualty department of your nearest hospital:

• A severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing).

This is a rare but side effect, which affects more than 1 in 10,000 patients but fewer than 1 in 1,000 patients.

• Muscle pain or cramps, leg pain, back pain.

• Insomnia, headache, dizziness.

• Increased symptoms such as muscle pain, weakness and swelling of the skin, especially on the feet, legs, arms and buttocks, with joint swelling, stiffness, muscle weakness, bruising, inflammation of the skin, rash, edema of the skin, sensitivity to light, dry skin, flushing, sweating, hair loss.

• Pain in the arms, shoulders, hips, knees or other joints, joint swelling, stiffness, muscle weakness.

• Frequent urination including at night, abnormal kidney function including swelling of the kidneys, urinary infection, sugar in the urine.

• Decreased visual acuity, impotence.

• Swelling of the face, fever.

Rare (more than 1 in 10,000 patients and less than 1 in 100 patients):

• Hepatitis (inflammation of the liver), abnormal liver function tests.

Not known (the frequency cannot be estimated from the available data):

• Abnormal muscle breakdown (rhabdomyolysis) with symptoms such as muscle pain, weakness and swelling which can lead to kidney problems (renal can become dark).

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

How to store
Keep out of the reach and sight of children.

Do not use Losartan HCT tablets after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

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.

Further information
What Losartan HCT tablets contain

• The active substances are losartan potassium and hydrochlorothiazide.

Each Losartan HCT 50mg/12.5mg tablet contains 50mg losartan potassium and 12.5mg hydrochlorothiazide.

Each Losartan HCT 100mg/25mg tablet contains 100mg losartan potassium and 25mg hydrochlorothiazide.

• The other ingredients are:
  • Tablet core: mannitol (E421), microcrystalline cellulose, stearic acid, magnesium stearate.

  • Film-coating: hypromellose (3M), macrogol 400, hydroxypropyl cellulose, titanium dioxide (E171), macrogol 400.

What Losartan HCT tablets look like and contents of the pack
Losartan potassium/hydrochlorothiazide 50mg/12.5mg tablets are white, round, biconvex, 8mm film-coated tablets, scored on both sides, with side scores: “LH1” is marked on one side.

Losartan potassium/hydrochlorothiazide 100mg/25mg tablets are white, round, biconvex, 8mm film-coated tablets, scored on both sides, with side scores: “LH2” is marked on one side.

Pack size
28 film-coated tablets

Marketing Authorisation Holder
Actavis Group PTC, ICY
Reykjavikurvegur 76-78
220 Hafnarfjörður
Iceland

Manufacturer
Actavis H
Reykjavikurvegur 78, 105-220 Hafnarfjörður
Iceland

This leaflet was last revised in May 2011

If you would like a leaflet with larger text, please contact 01271 311257.