

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### TENLOP H

50/12.5mg Film-coated Tablets, 100/25mg Film-coated Tablets

LOSARTAN POTASSIUM/HYDROCHLOROTHIAZIDE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

1. What TENLOP H is and what it is used for
2. Before you take TENLOP H
3. How to take TENLOP H
4. Possible side effects
5. How to store TENLOP H

#### 1. WHAT TENLOP H IS AND WHAT IS IT USED FOR

TENLOP H tablets are a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide).

TENLOP H tablets are indicated for the treatment of essential hypertension (high blood pressure).

#### 2. BEFORE YOU TAKE TENLOP H

##### **Do not take TENLOP H tablets if you**

- are **allergic** to losartan, hydrochlorothiazide or to any of the other ingredients of this medicine
- are **allergic** (hypersensitive) to other sulfonamide-derived substances (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 TENLOP H tablets in early pregnancy – see pregnancy section)
- have severely impaired **kidney** function 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 **gout**.
- have **diabetes** or impaired **kidney** function and you are treated with a blood pressure lowering medicine containing **aliskiren**.
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### **Warnings and precautions**

Talk to your doctor or pharmacist before taking TENLOP H tablets if you

- have previously **suffered from swelling** of the face, lips, throat or tongue
- take **diuretics** (water pills)
- 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 **narrowing of the arteries** (atherosclerosis), **angina pectoris** (chest pain due to poor heart function)
- have ‘**aortic or mitral valve stenosis**’ (narrowing of the valves of the heart) or ‘**hypertrophic cardiomyopathy**’ (a disease causing thickening of heart muscle)
- have a history of mild to moderate **liver** impairment
- are **diabetic**
- have had **gout**
- have or 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 TENLOP H tablets.
- suffer from **primary hyperaldosteronism** (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland).
- are taking any of the following **medicines** used to treat high blood pressure:
  - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems
  - aliskiren

Your doctor may check your kidney function, blood pressure and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading “Do not take TENLOP H tablets if you”

You must tell your doctor if you think you are (or might become) pregnant. TENLOP H 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).

### **Children and adolescents**

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

### **Other medicines and TENLOP H tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Diuretic agents such as the hydrochlorothiazide contained in TENLOP H tablets may interact with other medicines.

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

Special precautionary measures (e.g. blood tests) may be appropriate if you take potassium supplements, 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 insulins).

Your doctor may need to change your dose and/or to take other precautions:

- If you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take TENLOP H tablets if you” and “Warnings and precautions”).

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

- other medicines to reduce your blood pressure,
- steroids,
- medicines to treat cancer,
- pain killers,
- drugs for treatment of infections, including fungal infections,
- arthritis medicines,
- resins used for high cholesterol, such as colestyramine,
- medicines which relax your muscles,
- sleeping tablets
- opioid medicines such as morphine
- “pressor amines” such as adrenaline (epinephrine) or other drugs from the same group.
- oral agents for diabetes or insulins
- anticholinergic agents (e.g. atropine, biperiden).
- antipsychotics
- antidepressants
- carbamazepine

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

### ***TENLOP H tablets with food and drink and alcohol***

You are advised not to drink alcohol whilst taking these tablets: alcohol and TENLOP H tablets may increase each other’s effects.

Dietary salt in excessive quantities may counteract the effect of TENLOP H tablets.

TENLOP H tablets may be taken with or without food.

### ***Pregnancy and breast-feeding***

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### ***Pregnancy***

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking TENLOP H tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of TENLOP H tablets. TENLOP H tablets are not recommended during 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. TENLOP H 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.

#### ***Use in elderly patients***

TENLOP H tablets work equally well in and are equally well tolerated by most older 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.

### ***3. HOW TO TAKE TENLOP H***

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will decide on the appropriate dose of TENLOP H tablets depending on your condition and whether you are taking other medicines. It is important to continue taking TENLOP H tablets for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

### ***High Blood Pressure***

The recommended usual dose of TENLOP H tablets for most patients with high blood pressure is 1 tablet of TENLOP H 50mg/12.5mg per day to control blood pressure over the 24-hour period. This can be increased to 2 tablets once daily of losartan/hydrochlorothiazide 50mg/12.5mg film-coated tablets or changed to 1 tablet daily of losartan/hydrochlorothiazide 100mg/25mg film-coated tablets (a stronger strength) per day. The maximum daily dose is 2 tablets per day of losartan/hydrochlorothiazide 50mg/12.5mg film-coated tablets or 1 tablet daily of losartan/hydrochlorothiazide 100mg/25mg film-coated tablets.

### ***If you take more TENLOP H 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 TENLOP H tablets***

Try to take TENLOP H tablets daily as prescribed. Do not take a double dose to make up for a forgotten dose. Just resume your usual schedule.

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

### ***4. POSSIBLE SIDE EFFECTS***

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience the following, stop taking TENLOP H 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 serious but rare side effect, which affects more than 1 out of 10,000 patients but fewer than 1 out of 1,000 patients. You may need urgent medical attention or hospitalisation.

The following side effects have been reported:

**Common** (may affect up to 1 in 10 people)

- Cough, upper airway infection, congestion in the nose, sinusitis, sinus disorder,
- Diarrhoea, abdominal pain, nausea, indigestion,
- Muscle pain or cramps, leg pain, back pain,
- Insomnia, headache, dizziness,
- Weakness, tiredness, chest pain,
- Increased potassium levels (which can cause an abnormal heart rhythm), decreased haemoglobin levels,
- Changes in kidney function including kidney failure,
- Low blood sugar (hypoglycaemia).

**Uncommon** (may affect up to 1 in 100 people)

- Anaemia, red or brownish spots on the skin (sometimes especially on the feet, legs, arms and buttocks, with joint pain, swelling of the hands and feet and stomach pain), bruising, reduction in white blood cells, clotting problems, reduced number of platelets,
- Loss of appetite, increased uric acid levels or frank gout, increased blood sugar levels, abnormal blood electrolyte levels,
- Anxiety, nervousness, panic disorder (recurring panic attacks), confusion, depression, abnormal dreams, sleep disorders, sleepiness, memory impairment,
- Pins and needles or similar sensations, pain in the extremities, trembling, migraine, fainting,
- Blurred vision, burning or stinging in the eyes, conjunctivitis, worsening eyesight, seeing things in yellow,
- Ringing, buzzing, roaring or clicking in the ears, vertigo
- Low blood pressure, which may be associated with changes in posture (feeling light-headed or weak when you stand up), angina (chest pain), abnormal heartbeat, cerebrovascular accident (TIA, “mini-stroke”), heart attack, palpitations,
- Inflammation of blood vessels, which is often associated with a skin rash or bruising,
- Sore throat, breathlessness, bronchitis, pneumonia, water on the lungs (which causes difficulty breathing), nosebleed, runny nose, congestion,
- Constipation, wind, stomach upsets, stomach spasms, vomiting, dry mouth, inflammation of a salivary gland, toothache,
- Jaundice (yellowing of the eyes and skin), inflammation of the pancreas,
- Hives, itching, inflammation of the skin, rash, redness 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 inflammation of the kidneys, urinary infection, sugar in the urine,
- Decreased sexual appetite, impotence,
- Swelling of the face, localised swelling (oedema), fever.

**Rare** (may affect up to 1 in 1,000 people)

- Hepatitis (inflammation of the liver), abnormal liver function tests

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

- Flu-like symptoms and feeling of general discomfort and illness
- Generally feeling unwell (malaise)
- Low levels of sodium in the blood (hyponatraemia)
- Abnormal muscle breakdown (rhabdomyolysis) with symptoms such as muscle pain, weakness and swelling which can lead to kidney problems (urine can become dark)
- Disturbed taste (dysgeusia)
- Dose-related orthostatic effects such as lowering of blood pressure appearing when rising from a lying or sitting position,
- Cutaneous lupus erythematosus, which is identified by a rash that may appear on the face, neck, and scalp.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

### **5. HOW TO STORE TENLOP H**

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.