

## Package leaflet: Information for the patient

# Losanet-H 50 mg/12.5 mg tablets

# Losanet-H Forte 100 mg/12.5 mg tablets

# Losanet-H Forte 100 mg/25 mg tablets

## Losartan potassium/ hydrochlorothiazide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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.

### What is in this leaflet

1. What Losanet-H and Losanet H-Forte are and what they are used for
2. What you need to know before you take Losanet-H and Losanet H-Forte
3. How to take Losanet-H and Losanet H-Forte
4. Possible side effects
5. How to store Losanet-H and Losanet H-Forte
6. Contents of the pack and other information

### 1. What Losanet-H and Losanet H-Forte are and what they are used for

Losanet-H and Losanet H-Forte are a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide). Angiotensin II is a substance produced in the body which binds to receptors in blood vessels, causing them to tighten. This results in an increase in the blood pressure. Losartan prevents the binding of angiotensin II to these receptors, causing the blood vessels to relax which in turn lowers the blood pressure. Hydrochlorothiazide works by making the kidneys pass more water and salt. This also helps to reduce blood pressure.

Losanet-H and Losartan H-Forte are indicated for the treatment of essential hypertension (high blood pressure).

### 2. What you need to know before you take Losanet-H and Losanet H-Forte

#### Do not take Losanet-H and Losanet H-Forte

- If you are allergic (hypersensitive) to losartan potassium, hydrochlorothiazide or to any of the other ingredients in this medicine (listed in section 6)
- If you 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)
- If you have severely impaired liver function
- If you have low potassium, low sodium or high calcium levels which cannot be corrected by treatment
- If you are suffering from gout
- If you are, for more than 3 months, pregnant (It is also better to avoid Losanet-H and Losanet H-Forte in early pregnancy - see Pregnancy)
- If you have severely impaired kidney function or your kidneys are not producing any urine
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren

If any of the above applies to you, do not take Losanet-H or Losanet H-Forte and talk to your doctor.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Losanet-H or Losanet H-Forte. If you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Losanet-H or Losanet H-Forte. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this. You must tell your doctor if you think you are (or might become) pregnant. This medicine 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 (see pregnancy section).

It is important to tell your doctor before taking Losanet-H or Losanet H-Forte:

- If you have previously suffered from swelling of the face, lips, throat or tongue
- If you take diuretics (water pills)
- If you are on a salt-restricted diet
- If you have or have had severe vomiting and/or diarrhoea
- If you have heart failure
- If your liver function is impaired (see section 2 "Do not take Losanet-H and Losanet H-Forte")
- If you have narrow arteries to your kidneys (renal artery stenosis) or only have one functioning kidney, or you have recently had a kidney transplant
- If you have narrowing of the arteries (atherosclerosis), angina pectoris (chest pain due to poor heart function)
- If you have 'aortic or mitral valve stenosis' (narrowing of the valves of the heart) or 'hypertrophic cardiomyopathy' (a disease causing thickening of heart muscle)
- If you are diabetic
- If you have had gout
- If you have or have had an allergic condition, asthma or a condition that causes joint pain, skin rashes and fever (systemic lupus erythematosus)
- If you have high calcium or low potassium levels or you are on a low potassium diet
- If you 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 potassium and hydrochlorothiazide tablets
- If you 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)
- If you 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
- If you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Losanet-H and Losanet H-Forte.
- If you are taking other medicines that may increase serum potassium (see section 2 "Other medicines and Losanet-H and Losanet-H Forte")

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 Losanet-H and Losanet H-Forte".

If any of the above applies to you, ask your doctor.

#### Children and adolescents

There is no experience with the use of Losanet-H or Losanet H-Forte in children. Therefore, Losanet-H and Losanet H-Forte should not be given to children.

#### Other medicines and Losanet-H and Losanet H-Forte

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

Tell your doctor if you are taking potassium supplements, potassium-containing salt substitutes, potassium-sparing medicines, or other medicines that may increase serum potassium (e.g., trimethoprim-containing medicines), as the combination with Losanet-H and Losanet-H Forte are not advisable.

Diuretic agents such as the hydrochlorothiazide contained in Losanet-H and Losanet H-Forte may interact with other medicines.

Preparations containing lithium should not be taken with Losanet-H and Losanet H-Forte 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, medicines for the treatment of gout, medicines to control heart rhythm or for diabetes (oral agents or insulins).

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 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 or other drugs from the same group
- Oral agents for diabetes 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 Losanet-H and Losanet H-Forte" and "Warnings and precautions").

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

#### Losanet-H and Losanet H-Forte with food, drink and alcohol

You can take Losanet-H and Losanet H-Forte with or without food.

You are advised not to drink alcohol whilst taking these tablets: alcohol and Losanet-H and Losanet H-Forte tablets may increase each other's effects.

Dietary salt in excessive quantities may counteract the effect of Losanet-H and Losanet H-Forte tablets.

#### Pregnancy and breast-feeding

##### Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking this medicine before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Losanet-H and Losanet H-Forte.

This medicine is not recommended during pregnancy and must not be taken if you are, for more than 3 months, pregnant, as it may cause serious harm to your baby if it is used after the third month of pregnancy.

##### Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. This medicine is not recommended for mothers who are breastfeeding, and your doctor may choose another treatment for you if you wish to breast-feed.

##### Use in elderly patients

Losanet-H and Losanet H-Forte works equally well in and is 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 an automobile or operating dangerous machinery) until you know how you tolerate your medicine.

##### Losanet-H and Losanet H-Forte contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### 3. How to take Losanet-H

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

#### Taking this medicine

The tablets should be swallowed with a glass of water.

#### High Blood Pressure

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

Losanet H Forte 100/12.5 is available for those patients titrated to 100 mg of Losanet who require additional blood pressure control.

#### If you take more Losanet-H and Losanet H-Forte than you should

In case of an overdose, contact your doctor immediately so that medical attention may be given promptly.

Overdose can cause a drop in blood pressure, palpitations, slow pulse, changes in blood composition and dehydration.

#### If you forget to take Losanet-H and Losanet H-Forte

Try to take Losanet-H and Losanet H-Forte daily as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule.

### 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 Losanet-H and Losanet H-Forte tablets and tell your doctor immediately or go to 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. You may need urgent medical attention or hospitalization.

#### 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
- Too low sugar in the blood (hypoglycaemia)
- 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

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

- 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, obstipation, 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 tract infection, sugar in the urine

- Decreased sexual appetite, impotence

- Swelling of the face, localised swelling (oedema), fever

*Rare (may affect up to 1 in 1000 people)*

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

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

- Flu-like symptoms
- Unexplained muscle pain with dark (tea-colored) urine (rhabdomyolysis)
- Low levels of sodium in the blood (hyponatraemia)
- Generally feeling unwell (malaise)
- Disturbed taste (dysgeusia)
- Skin and lip cancer (Non-melanoma skin cancer)
- decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma).

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 Losanet-H and Losanet H-Forte

- 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 blister and the outer packaging. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Keep away from humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### 6. Contents of the pack and other information

#### What Losanet-H and Losanet H-Forte contains

The active substances in Losanet-H and Losanet H-Forte are losartan potassium and hydrochlorothiazide.

- Losanet-H 50 mg/12.5 mg: Each tablet contains 50 mg losartan potassium and 12.5 mg hydrochlorothiazide.

- Losanet-H Forte 100 mg/12.5 mg: Each tablet contains 100 mg losartan potassium and 12.5 mg hydrochlorothiazide

- Losanet-H Forte 100 mg/25 mg: Each tablet contains 100 mg losartan potassium and 25 mg hydrochlorothiazide

The other ingredients are: microcrystalline cellulose, lactose monohydrate, pregelatinized starch, magnesium stearate.

#### What Losanet-H and Losanet H-Forte looks like and contents of the pack

Losanet-H and Losanet H-Forte tablets are white to off-white round tablets.

- Losanet-H 50 mg/12.5 mg is available in boxes containing 30 tablets.

- Losanet-H Forte 100 mg/12.5 mg is available in boxes containing 30 tablets.

- Losanet-H Forte 100 mg/25 mg is available in boxes containing 30 tablets.

Not all strengths may be marketed.

#### Marketing Authorisation Holder and Manufacturer

Pharmaline s.a.l. – Lebanon

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Losanet-H 50mg/12.5 mg Registration No for Lebanon: 195019/04

Losanet-H Forte 100 mg/12.5 mg, Reg No Lebanon: 222489/08

Losanet-H Forte 100 mg/25 mg, Reg No Lebanon: 24372/06

#### This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.