

Package leaflet : Information for the user

Losartan/Hydrochlorothiazide Bluefish 50 mg/12.5 mg and 100 mg/25 mg film-coated 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 of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Losartan/Hydrochlorothiazide Bluefish is and what it is used for
2. What you need to know before you take Losartan/Hydrochlorothiazide Bluefish
3. How to take Losartan/Hydrochlorothiazide Bluefish
4. Possible side effects.
5. How to store Losartan/Hydrochlorothiazide Bluefish
6. Contents of the pack and other information

1. What Losartan/Hydrochlorothiazide Bluefish is and what it is used for

Losartan/Hydrochlorothiazide Bluefish is a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide).

Losartan/Hydrochlorothiazide Bluefish is indicated for the treatment of essential hypertension (high blood pressure).

2. What you need to know before you take Losartan/Hydrochlorothiazide Bluefish

Do not take Losartan/Hydrochlorothiazide Bluefish

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

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Losartan/Hydrochlorothiazide Bluefish

- 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
 - 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

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 Losartan Hydrochlorothiazide Bluefish”

You must tell your doctor if you think that you are (or might become) pregnant. Losartan/Hydrochlorothiazide Bluefish 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).

Children and adolescents

There is no experience with the use of Losartan/Hydrochlorothiazide Bluefish in children. Therefore, Losartan/Hydrochlorothiazide Bluefish should not be given to children

Other medicines and Losartan/Hydrochlorothiazide Bluefish

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

It is especially important to tell the doctor if you are taking any of the following medicines. Your doctor may need to change your dose and/or to take other precautions:

- potassium supplements, potassium sparing medicines, or potassium-containing salt substitutes
- rifampicin, a drug used in the treatment of tuberculosis (TB)
- fluconazole, a drug used for treating fungal infections such as thrush
- non-steroidal, anti-inflammatory painkillers (such as ibuprofen, naproxen or diclofenac), COX-2 inhibitors (such as celecoxib, etoricoxib or lumiracoxib) or aspirin
- barbiturates, sedative drugs which may be used in the treatment of sleeplessness or epilepsy
- drugs which induce hypotension, such as tricyclic antidepressants, antipsychotics, baclofene and amifostine
- narcotics, morphine like drugs used for severe pain
- medicines to control heart rhythm or antidiabetic drugs (medicines for the treatment of diabetes), including oral agents to lower blood sugar and insulin, such as metformin
- other drugs used to reduce blood pressure
- other diuretics (“water tablets”)
- some laxatives
- medicines for the treatment of gout, such as probenecid, sulfinpyrazone and allopurinol
- medicines to treat cancer
- medicines which relax your muscles, such as tubocurarine
- immunosuppressant drug such as cyclosporine
- resins which are used to reduce high cholesterol levels, such as colestyramine and colestipol resins
- ACTH, used to test whether your adrenal glands are working properly
- corticosteroids, used to treat various conditions including rheumatism, arthritis, allergic conditions, certain skin diseases, asthma or certain blood disorders
- pressor amines such as adrenaline used for the treatment of hypotension, shock, cardiac failure, asthma or allergies
- lithium, a drug used to treat certain mental disorders should not be taken without close supervision by your doctor.
- carbamazepine, a drug used for treating epilepsy
- an ACE-inhibitor or aliskiren (see also information under the heading “Do not take Losartan/Hydrochlorothiazide Bluefish and “Warnings and precautions”

Please also inform your doctor when it is planned to apply iodine contrast media about taking Losartan/Hydrochlorothiazide Bluefish.

Losartan/Hydrochlorothiazide Bluefish with food, drink and alcohol

You are advised not to drink alcohol whilst taking these tablets: alcohol and Losartan/Hydrochlorothiazide Bluefish may increase each other’s effects.

Dietary salt in excessive quantities may counteract the effect of Losartan/Hydrochlorothiazide Bluefish.

Losartan/Hydrochlorothiazide Bluefish may be taken with or without food.

Pregnancy and breast-feeding

If you are pregnant or breast feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking any 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 Losartan/Hydrochlorothiazide Bluefish before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Losartan/Hydrochlorothiazide Bluefish. Losartan/Hydrochlorothiazide Bluefish is 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.

Breast feeding

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

Driving and using machines

Losartan/Hydrochlorothiazide Bluefish may cause dizziness and drowsiness, particularly in the beginning of treatment or when the dose is increased. You should not perform tasks which may require special attention (for example driving or operating machinery) until you know how you tolerate this medicine.

Losartan/Hydrochlorothiazide Bluefish 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 Losartan/Hydrochlorothiazide Bluefish

Always take Losartan/Hydrochlorothiazide Bluefish 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 Losartan/Hydrochlorothiazide Bluefish depending on your condition and whether you are taking other medicines. It is important to continue taking Losartan/Hydrochlorothiazide Bluefish 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/Hydrochlorothiazide Bluefish for most patients with high blood pressure is 1 tablet of Losartan/Hydrochlorothiazide Bluefish 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 Losartan / Hydrochlorothiazide 50 mg/12.5 mg or changed to 1 tablet daily of Losartan / Hydrochlorothiazide 100 mg/25 mg (a stronger strength) per day. The maximum daily dose is 2 tablets per day of Losartan / Hydrochlorothiazide 50 mg/12.5 mg or 1 tablet daily of Losartan / Hydrochlorothiazide 100 mg/25 mg tablets.

If you take more Losartan/Hydrochlorothiazide Bluefish than you should

In case of an overdose, contact your doctor immediately so that medical attention may be given promptly. Over dosage can cause a drop in blood pressure, palpitations, slow pulse, changes in blood composition, and dehydration.

If you forget to take Losartan/Hydrochlorothiazide Bluefish

If you forget to take your medicine, take your dose when you remember and then take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose. If you are worried, ask your doctor or pharmacist for advice.

If you stop taking Losartan/Hydrochlorothiazide Bluefish

Do not stop taking your tablets, even if you are feeling well, unless your doctor tells you.

If you have any further questions on the use of this medicine, 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 Losartan/Hydrochlorothiazide Bluefish 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 10000 patients but fewer than 1 out of 1000 patients. You may need urgent medical attention or hospitalization.

Losartan/Hydrochlorothiazide Bluefish may cause a reduction in the number of white blood cells and your resistance to infection may be decreased. If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems you should see your doctor immediately. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis). It is important to inform your doctor about your medicines.

This is an uncommon side effect (affects 1 to 10 users in 1000).

The following side effects have been reported:

Common: (may affects 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.

Uncommon: (may affects 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
- 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,,
- 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, fever.

Rare: (may affects 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

- Disturbed taste

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. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Losartan/Hydrochlorothiazide Bluefish

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 carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 to protect the environment.

6. Content of the pack and other information

What Losartan/Hydrochlorothiazide Bluefish contains

The active substances are losartan potassium and hydrochlorothiazide.

Losartan/Hydrochlorothiazide Bluefish 50 mg/12.5 mg film-coated tablet contains 50mg of losartan potassium and 12.5 mg of hydrochlorothiazide.

Losartan/Hydrochlorothiazide Bluefish 100 mg/25 mg film-coated tablet contains 100 mg of losartan potassium and 25 mg of hydrochlorothiazide.

The other ingredients are lactose monohydrate, pregelatinised maize starch, microcrystalline cellulose, magnesium stearate. The tablets are coated with hydroxypropylcellulose, hypromellose, talc, titanium dioxide, yellow iron oxide.

What Losartan/Hydrochlorothiazide Bluefish looks like and contents of the pack

Losartan/Hydrochlorothiazide Bluefish 50 mg/12.5 mg are Yellow and oblong with a score line.

Losartan/Hydrochlorothiazide Bluefish 100 mg/25 mg are Yellow and round with a score line.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

The tablets are packed in blister.

Pack sizes:

50/12.5 mg: 14, 28, 56, 90 and 98 tablets

100/25 mg: 28, 56, 90 and 98 tablets

Not all pack size may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Bluefish Pharmaceuticals AB

P.O. Box 49013

100 28 Stockholm

Sweden

Manufacturer

Bluefish Pharmaceuticals AB

Gävlegatan 22

113 30 Stockholm

Sweden

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of MS	Name of medicinal product
Austria	Losartan/Hydrochlorothiazide Bluefish 50 mg/12,5 mg & 100 mg/25 mg Filmtabletten
Denmark	Losartan/Hydrochlorothiazide Bluefish 50 mg/12,5 mg & 100 mg/25 mg
Spain	Losartan/Hydrochlorothiazide Bluefish 50 mg/12,5 mg & 100 mg/25 mg comprimidos recubiertos con película
Ireland	Losartan/Hydrochlorothiazide Bluefish 50 mg/12.5 mg & 100 mg/25 mg film-coated tablets
Iceland	Losartan/Hydrochlorothiazide Bluefish 50/12,5 mg flmuhuaa tafla Losartan/Hydrochlorothiazide Bluefish 100/25 mg flmuhuaa tafla

The Netherlands	Losartankalium/Hydrochloorthiazide Bluefish 50 mg/12,5 mg & 100 mg/25 mg filmomhulde tabletten
Norway	Losartan/Hydrochlorothiazide Bluefish
Poland	Losartan HCT Bluefish
Portugal	Losartan/Hydrochlorothiazide Bluefish
Sweden	Losartan/Hydrochlorothiazide Bluefish 50 mg/12,5 mg & 100 mg/25 mg filmdragerade tabletter

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