



PACKAGE LEAFLET: INFORMATION FOR THE USER
Bellisin 2.5 mg TABLETS
Bellisin 5 mg TABLETS
Bellisin 10 mg TABLETS
Bellisin 20 mg TABLETS
lisinopril

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. See section 4.

- What is in this leaflet:**
- 1. What Bellisin Tablets are and what they are used for**
 - 2. What you need to know before you take Bellisin Tablets**
 - 3. How to take Bellisin Tablets**
 - 4. Possible side effects**
 - 5. How to store Bellisin Tablets**
 - 6. Contents of the pack and other information**

1. What Bellisin Tablets are and what they are used for

Bellisin Tablets contains a medicine called lisinopril. This belongs to a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors. ACE inhibitors are vasodilators (drugs which widen the blood vessels) making it easier for the heart to pump blood around the body. Bellisin Tablets can be used for the following conditions:

- To treat high blood pressure (hypertension)
- To treat heart failure
- If you have recently had a heart attack (myocardial infarction)
- To treat kidney problems caused by Type II diabetes in people with high blood pressure

Bellisin Tablets work by making your blood vessels widen. This helps to lower your blood pressure. It also makes it easier for your heart to pump blood to all parts of your body.

- 2. What you need to know before you take Bellisin Tablets**
- Do not take Bellisin Tablets**
- If you are allergic (hypersensitive) to lisinopril or any of the other ingredients of this medicine (listed in section 6)
 - if you have ever had an allergic reaction to another ACE inhibitor medicine. The allergic reaction may have caused swelling of the hands, feet, ankles, face, lips, tongue or throat. It may also have made it difficult to swallow or breathe (angioedema).
 - if a member of your family has had severe allergic reactions (angioedema) to an ACE inhibitor or you have had severe allergic reactions (angioedema) without a known cause.
 - if you are more than 3 months pregnant. (It is also better to avoid Bellisin Tablets in early pregnancy – see Pregnancy section).
 - if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If you develop a dry cough which is persistent for a long time after starting treatment with Bellisin Tablets, talk to your doctor.

- Warnings and precautions**
- Talk to your doctor or pharmacist before taking Bellisin Tablets :
- if you have a narrowing (stenosis) of the aorta (an artery in your heart) or a narrowing of the heart valve (mitral valves)
 - if you have a narrowing (stenosis) of the kidney artery
 - if you have an increase in the thickness of the heart muscle (known as hypertrophic cardiomyopathy)
 - if you have problems with your blood vessels (collagen vascular disease)
 - if you have low blood pressure. You may notice this as feeling dizzy or light-headed, especially when standing up
 - if you have kidney problems or you are having kidney dialysis
 - if you have liver problems
 - if you have diabetes
 - if you have recently had diarrhoea or vomiting (being sick)
 - if your doctor has told you to control the amount of salt in your diet
 - if you have high levels of cholesterol and you are having a treatment called 'LDL apheresis'
 - you must tell your doctor if you think you are (or might become) pregnant. Bellisin 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)
 - if you are of black origin as Bellisin Tablets may be less effective. You may also more readily get the side effect 'angioedema' (a severe allergic reaction)
 - if you are taking any of the following medicines used to treat high blood pressure:
 - an angiotensin II receptor blocker (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), 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 Bellisin Tablets"

Treatment for allergies such as insect stings
Tell your doctor if you are having or are going to have treatment to lower the effects of an allergy such as insect

stings (desensitisation treatment). If you take Bellisin Tablets while you are having this treatment, it may cause a severe allergic reaction.

Operations
If you are going to have an operation (including dental surgery), tell your doctor or dentist that you are taking Bellisin tablets. This is because you can get low blood pressure (hypotension) if you are given certain local or general anaesthetics while you are taking Bellisin Tablets.

Children and adolescents
Bellisin Tablets have been studies in children. For more information, talk to your doctor. Bellisin Tablets are not recommended in children under 6 years of age or in any child with severe kidney problems.

Other medicines and Bellisin Tablets
Tell your doctor or pharmacist if you are taking, or have recently taken or might take any other medicines. This is because Bellisin Tablets can affect the way some medicines work and some medicines can have an effect on Bellisin Tablets.

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

If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings "Do not take Bellisin Tablets" and "Warnings and precautions")

- In particular tell your doctor or pharmacist if you are taking any of the following medicines:
- Water tablets (diuretic medicines)
 - Medicines to break up blood clots (usually given in hospital)
 - Beta-blocker medicines, such as atenolol and propranolol
 - Nitrate medicines (for heart problems)
 - Non-steroidal anti-inflammatory drugs (NSAIDs) used to treat pain and arthritis
 - Aspirin (Acetylsalicylic acid), if you are taking more than 3 grams each day
 - Medicines for depression and for mental problems, including lithium.
 - Potassium tablets or salt substitutes that have potassium in them
 - Insulin or medicines that you take by mouth for diabetes
 - Medicines used to treat asthma
 - Medicines to treat nose or sinus congestion or other cold remedies (including those you can buy in the pharmacy)
 - Medicines to suppress the body's immune response (immunosuppressants)
 - Allopurinol (for gout)
 - Procainamide (for heart beat problems)
 - Medicines that contain gold, such as sodium aurothiomalate, which may be given to you as an injection

Taking Bellisin Tablets with food and drink
Do not drink alcohol while taking Bellisin 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 Bellisin Tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Bellisin Tablets. Bellisin 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.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Bellisin 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.

Driving and using machines
Some people feel dizzy or tired when taking this medicine. If this happens to you, do not drive or use any tools or machines. You must wait to see how your medicine affects you before trying these activities.

3. How to take Bellisin Tablets
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Once you have started taking Bellisin Tablets your doctor may take blood tests. Your doctor may then adjust your dose so you take the right amount of medicine for you.

Taking your medicine

- Swallow the tablet whole with a drink of water.
- Try to take your tablets at the same time each day. Your tablets can be taken before or after food.
- Keep taking Bellisin Tablets for as long as your doctor tells you to, it is a long term treatment. It is important to keep taking Bellisin Tablets every day.

Taking your first dose
Take special care when you have your first dose of Bellisin Tablets or if your dose is increased. It may cause a greater fall in blood pressure than later doses. This may make you may feel light headed or dizzy. If this happens, it may help to lie down. If you are concerned please contact your doctor as soon as possible.

Adults
Your dose depends on your medical condition and whether you are taking any other medicines. Your doctor will tell you how many tablets to take each day. Check with your doctor or pharmacist if you are unsure.

For high blood pressure
The recommended starting dose is 10mg once a day. The usual long-term dose is 20mg once a day.

For heart failure
The recommended starting dose is 2.5mg once a day. The long-term dose is 5 to 35mg once a day.

After a heart attack
The recommended starting dose is 5 mg within 24 hours of your attack and 5 mg one day later. The usual long-term dose is 10 mg once a day.

For kidney problems caused by diabetes
The recommended dose is either 10 mg or 20 mg once a day. If you are elderly, have kidney problems or are taking diuretic medicines your doctor may give you a lower dose than the usual dose.

Use in children and adolescents (6 to 16 years old) with high blood pressure
Bellisin is not recommended for children under 6 years or in any children with severe kidney problems. The doctor will work out the correct dose for your child. The dose depends on the child's body weight. For children who weigh between 20 kg and 50 kg, the recommended starting dose is 2.5 mg once a day and maximum dose is 20 mg daily. For children who weigh more than 50 kg, the recommended starting dose is 5 mg once a day and maximum dose is 40 mg daily.

If you take more Bellisin Tablets than you should
If you take more Bellisin Tablets than prescribed by your doctor, talk to a doctor or go to nearest hospital casualty department immediately. The following effects are most likely to happen: dizziness, palpitations.

If you forget to take Bellisin Tablets
If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for the forgotten doses. If

If you stop taking Bellisin Tablets
Do not stop taking your tablets even if you feel well, unless your doctor tells you to. 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 any of the following happen, stop taking Bellisin Tablets and tell your doctor immediately or go to the casualty department at your nearest hospital.

- Severe allergic reactions. The signs may include sudden onset of:
 - Swelling of your face, lips, tongue or throat. This may make it difficult to swallow.
 - Severe or sudden swelling of your hands, feet and ankles.
 - Difficulty breathing.
 - Severe itching of the skin (with raised lumps).
- Severe skin disorders, like a sudden unexpected rash or burning, red or peeling skin.
- 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.

Other possible side effects
Common (may affect up to 1 in 10 people)

- headache
- feeling dizzy or light-headed, especially if you stand up quickly
- diarrhoea
- a dry cough that does not go away
- being sick (vomiting)
- kidney problems (shown in a blood test)

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

- mood changes
- change of colour in your fingers or toes (pale blue followed by redness) or numbness or tingling in your fingers or toes
- changes in the way things taste
- feeling sleepy
- having difficulty sleeping
- spinning feeling (vertigo)
- stroke
- fast heart beat
- runny nose
- feeling (nausea)
- stomach pain or indigestion
- skin rash or itching
- being unable to get an erection (impotence)
- feeling tired or feeling weak (loss of strength)
- a very big drop in blood pressure may happen in people with the following conditions: coronary heart disease; narrowing of the aorta (a heart artery), kidney artery or heart valves; an increase in the thickness of the heart muscle. If this happens to you, you may feel dizzy or light-headed, especially if you stand up quickly
- changes in blood tests that show how well your liver and kidneys are working
- heart attack
- seen and/or heard hallucinations

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

- feeling confused
- a lumpy rash (hives)
- dry mouth
- hair loss
- psoriasis (a skin problem)
- changes in the way things smell
- development of breasts in men
- changes to some of the cells or other parts of your blood. Your doctor may take blood samples from time to time to check whether Bellisin tablets has had any effect on your blood. The signs may include feeling tired, pale skin, a sore throat, high temperature (fever), joint and muscle pains, swelling of the joints or glands, or sensitivity to sunlight
- low levels of sodium in your blood (the symptoms may be tiredness, headache, nausea, vomiting)

- sudden renal failure

Very rare may affect up to 1 in 10,000 people)

- sinusitis (a feeling of pain and fullness behind your cheeks and eyes)
- wheezing
- low levels of sugar in your blood (hypoglycaemia). The signs may including feeling hungry or weak, sweating and a fast heart beat
- inflammation of the lungs. The signs include cough, feeling short of breath and high temperature (fever)
- yellowing of the skin or the whites of the eyes (jaundice)
- inflammation of the liver. This can cause loss of appetite, yellowing of the skin and eyes, and dark coloured urine
- inflammation of the pancreas. This causes moderate to severe pain in the stomach
- severe skin disorders. The symptoms include redness, blistering and peeling.
- sweating
- passing less water (urine) than normal or passing no water
- liver failure
- lumps
- inflamed gut

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

- symptoms of depression
- fainting

Side effects in children appear to be comparable to those seen in adults.

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 Bellisin Tablets
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 outer carton after EXP. The expiry date refers to the last day of that month.

Store in the original package.

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. Contents of the pack and other information
What Bellisin Tablets contains
The active substance is lisinopril (as lisinopril dihydrate).
Bellisin 2.5 mg Tablets – each tablet contains lisinopril dihydrate equivalent to 2.5 mg anhydrous lisinopril.
Bellisin 5 mg Tablets – each tablet contains lisinopril dihydrate equivalent to 5 mg anhydrous lisinopril.
Bellisin 10 mg Tablets – each tablet contains each tablet contains lisinopril dihydrate equivalent to 10 mg anhydrous lisinopril.
Bellisin 20 mg Tablets – each tablet contains each tablet contains lisinopril dihydrate equivalent to 20 mg anhydrous lisinopril.

The other ingredients are mannitol, calcium hydrogen phosphate anhydrous, maize starch, pregelatinised maize starch, magnesium stearate and iron oxide yellow (E172), 20 mg tablets also contain iron oxide red .

What Bellisin Tablets look like and contents of the pack
Bellisin 2.5mg Tablets are light yellow coloured uncoated, round tablets debossed with "2.5" on one side and plain on the other side.
Bellisin 5mg Tablets are light yellow coloured, capsule shaped, biconvex uncoated tablets debossed with "5" on one side of the score line and a deep scoreline on the other side.
Bellisin 10mg Tablets are light yellow coloured, capsule shaped, biconvex uncoated tablets debossed with "1" and "0" on either side of the scoreline and a deep scoreline on the other side.
Bellisin 20mg Tablets are light peach coloured, capsule shaped, biconvex uncoated tablets debossed with "2" and "0" on either side of the scoreline and a deep scoreline on the other side.

Bellisin tablets are available as a blister strip of 14, 28, 30, 50, 56, 98 and 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Ranbaxy Ireland Ltd., Spafield, Cork Road, Cashel, Co. Tipperary, Ireland.

Manufacturer:
Ranbaxy Ireland Ltd., Spafield, Cork Road, Cashel, Co. Tipperary, Ireland
or
Basics GmbH, Hemmelrather Weg 201, D-51377, Leverkusen, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:
Ireland: Bellisin 2.5mg/5mg/10mg/20mg Tablets
Spain: Lisinopril Ranbaxy 20mg comprimidos EFG
UK: Lisinopril 2.5mg/5mg/10mg/20mg Tablets

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Bellisin Tabs PIL
PI size : 140 x 400 mm
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RLL/PKGDEV : J01/Oct/2014-V01,
AK08/Jan/2015-V02, V03, AK24/Feb/2015-V04

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