PACKAGE LEAFLET: INFORMATION FOR THE USER

Zestan 2.5mg Tablets
Zestan 5mg Tablets
Zestan 10mg Tablets
Zestan 20mg Tablets

Lisinopril (as dihydrate)

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 Zestan is and what it is used for

Zestan tablets contain the active ingredient lisinopril. Lisinopril belongs to a group of medicines called ACE (angiotensin converting enzyme) inhibitors. These work by widening the blood vessels making it easier for the heart to pump blood to all parts of your body. This results in a lowering of blood pressure.

Zestan is used if:
- Your blood pressure is too high
- You are suffering from heart failure. This means that your heart does not pump your blood around the body as well as it used to, leading to disease-related symptoms such as tiredness, breathlessness or swelling of the ankles and feet
- You have had a heart attack [in this case Zestan is used as a short-term (6 weeks) treatment within 24 hours]
- You have kidney problems related to diabetes and high blood pressure.

2. What you need to know before you take Zestan

DO NOT take Zestan
- if you are allergic to lisinopril, any other medicine in the same group of drugs as lisinopril (ACE inhibitors), or any of the other ingredients of this medicine (listed in section 6).
- if you have previously suffered an allergic reaction to lisinopril or similar medicines (ACE inhibitors) involving symptoms like itching, nettle rash, wheezing or swelling of the hands, throat, mouth or eyelids.
- if you or any member of your family have a history of allergic reactions which caused difficulty in swallowing or breathing, swelling of the hands, feet or ankles, face, lips, tongue or throat (angioedema) or you have had angioedema in any other circumstances.
- if you are more than 3 months pregnant. (It is also better to avoid Zestan 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 have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.

Warnings and precautions
Talk to your doctor or pharmacist before taking Zestan
- 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 Zestan"

Tell your doctor or pharmacist if you have or have had any medical conditions or illnesses, especially any of the following:

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

Symptomatic hypotension (low blood pressure)
Zestan may rarely cause low blood pressure (symptomatic hypotension), especially at the beginning of the treatment.
This is more likely to occur in patients who
- are dehydrated or salt depleted, e.g. by the use of water tablets (diuretic therapy), dietary salt restriction (such as low-sodium diet), dialysis, diarrhoea or vomiting (see also section 2. "Other medicines and Zestan" and 4. "Possible side effects")
- have a severe form of high blood pressure caused by a kidney disease (renin-dependent hypertension) (see also section 2. "Other medicines and Zestan" and 4. "Possible side effects")
- have a serious heart failure (due to the use of high doses of water tablets, with or without impairment of the kidney function)
- have an ischaemic heart or cerebrovascular disease. Zestan could cause a heart attack (myocardial infarction) or stroke (cerebrovascular accident). Hence, these patients require careful medical supervision.

If you are at increased risk of suffering from a fall in blood pressure, your doctor will monitor you closely, especially when starting the treatment or changing the dose.

If your blood pressure falls too much
If your blood pressure falls too much you should lie down. If this persists, you may require medical help. A temporary fall in blood pressure does not mean you cannot continue the treatment with Zestan. Once your blood pressure has been restored, you may take Zestan as usual. However, in some cases a dose reduction or discontinuation of the treatment may be necessary. Talk to your doctor if your blood pressure sinks too much or frequently.

Heart valve and heart muscle diseases
Take special care with Zestan if you suffer from
- narrowing of the heart valves (mitral or aortic valve stenosis), which hinders the outflow of blood from the heart

– thickening of the heart muscle (hypertrophic cardiomyopathy)

Inform your doctor about your conditions and ask him/her for advice.

Hypersensitivity (allergic) reactions or angioedema

Uncommonly, ACE inhibitors (including lisinopril) have caused a life-threatening allergic reaction called angioedema. Very rarely fatal cases of angioedema have been reported in association with swelling of the voice box or tongue due to obstruction of the airways.

Stop taking Zestan and contact your doctor immediately if you experience any symptoms of angioedema, such as:

- swelling of the face, limbs, lips, tongue and/or throat
- difficulty swallowing
- difficulty breathing
- hives

You are more prone to angioedema if

- you are dark-skinned
- you have previously suffered from angioedema, even when this was not caused by an ACE inhibitor (see section "DO NOT take Zestan" above).

If you are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as the throat) may be increased:

- racecadotril, a medicine used to treat diarrhoea
- medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus)
- vildagliptin, a medicine used to treat diabetes

Life-threatening anaphylactoid (allergic) reactions have occurred in patients receiving the following treatments together with ACE inhibitors:

Tell your doctor that you are taking Zestan if you are on

- haemodialysis (with high-flux-membranes, e.g. AN 69)
- low-density lipoproteins (LDL) apheresis (a special technique to remove fat from the blood)
- desensitisation treatment, e.g. to bee and wasp poison (hymenoptera venom).

Ethnic differences

Like other ACE inhibitors, Zestan may be less effective in dark-skinned patients. Also, angioedema is more common in dark-skinned patients than in fair-skinned patients.

Kidney diseases

If you have a kidney disease or renal insufficiency your doctor may need to monitor your potassium and serum creatinine carefully and may adjust your lisinopril dosage (see also "How to take Zestan").

You should not take Zestan if you had a kidney transplant recently.

Special conditions may take an effect on your kidneys:

- In patients with heart failure, low blood pressure caused by ACE inhibitors may worsen the kidney function. Acute kidney failure has been reported in this situation, which was usually reversible.
- In some patients with narrowing of the blood vessels of the kidney (mono- or bilateral renal artery stenosis) who have been treated with ACE inhibitors, increases in blood urea and serum creatinine have been observed. This is more likely to occur in patients with impaired kidney function. These increases are usually reversible upon discontinuation of the treatment.

- Patients who also suffer from high blood pressure caused by diseases of the kidney arteries (renovascular hypertension) are more prone to low blood pressure and kidney insufficiency. These patients should begin the treatment under close medical supervision with low doses and careful dose adjustments. Treatment with water tablets (diuretics) should be stopped and the kidney function should be monitored during the first weeks of treatment with Zestan.
- Some hypertensive patients with no apparent pre-existing disease of the blood vessels of the kidneys (renal vascular disease) have developed increases in blood urea and serum creatinine. These increases have been usually minor and transient and it is more likely to occur in patients with pre-existing impairment of the kidney function. If this happens, your doctor may reduce your dose or prescribe you another medicine.

If your kidney function worsens, your doctor should evaluate your treatment carefully. He/she may ask you to stop taking Zestan.

Liver diseases
Very rarely, ACE inhibitors have been associated with a syndrome which starts with a yellowing of the skin and the whites of the eyes due to a blockage of the flow of bile from the liver to the gut (cholestatic jaundice) and progresses rapidly to death of the liver cells (liver necrosis) and (sometimes) to death.
If you develop jaundice you should stop taking Zestan and contact your doctor immediately. If your doctor notices an alteration of the liver enzymes, he/she may ask you to stop the treatment.

Alteration in the number of blood cells
Changes in the number of blood cells have been reported during treatment with ACE inhibitors (see section 4. "Possible side effects").
These changes may make you more prone to infections, bleeding or bruising. Please tell your doctor if you notice any of these signs. He/she will check your blood counts and might tell you to stop the treatment, if necessary. Some of these changes are reversible after stopping treatment with the ACE inhibitor.

You should take extreme care and ask your doctor for advice if
- you suffer from a disease of the connective tissues, such as blood, bone and cartilage (collagen vascular disease)
- you are taking any of the following medicines:
  - immunosuppressants (medicines to reduce the activity of the immune system, for example after an organ transplantation)
  - allopurinol (to treat gout and high levels of uric acid in the blood)
  - procainamide (to treat irregular heart beat)

This is especially important if your kidneys are not working well.

Increasing of the level of potassium in the blood (hyperkalaemia)
You are at increased risk of hyperkalaemia if
- your kidneys are not working well
- you suffer from diabetes mellitus
- you are taking other medicines associated with increases in serum potassium.

Nonetheless, if you need to take any of the mentioned agents, your doctor will have to monitor the level of potassium in your blood regularly (see section "Other medicines and Zestan" below).

Diabetes
If you are using oral anti-diabetic drugs or insulin your blood sugar level should be closely monitored during the first month (see section "Other medicines and Zestan" below). The dose of your anti-diabetic medicine may have to be adjusted.

Surgery or anaesthesia

If you are going into hospital for an operation or you are going to have dental surgery, tell your doctor or dentist you are taking Zestan before you are given an anaesthetic.

Lithium
You must tell your doctor, if you are taking lithium or lithium-containing medicines (used for the treatment of mania or depression). The combination of Zestan and lithium is generally not recommended (see section 2: Other medicines and Zestan).

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

The effect of this medicine may be different, if it is taken at the same time with certain other medicines. In particular, talk to your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines:

The following medicines may enhance the effect of Zestan, thus increasing the risk of low blood pressure (hypotension):
- water tablets (diuretics). If you are already taking water tablets, inform your doctor. He/She will tell you to stop this diuretic treatment 2 to 3 days before taking Zestan.
- other blood pressure lowering (antihypertensive) medicines
- glyceryl trinitrate (to treat angina and heart failure) and other nitrates
- other vasodilators (medicines which widen the blood vessels)
- tricyclic antidepressants (to treat depression)
- antipsychotics (to treat psychiatric illnesses/psychosis)
- anaesthetics

The following medicines may reduce the effect of Zestan:
- non-steroidal anti-inflammatory drugs (painkillers), including acetylsalicylic acid (aspirin), in doses more than 3 g per day. Chronic use of those painkillers may reduce the blood pressure-lowering effect of Zestan. Furthermore there is a risk of increasing the serum potassium and worsening of the kidney function, including kidney failure.
- sympathomimetics (medicines with a stimulant effect which raise the blood pressure)

Zestan may alter the effect of the following medicines:
- medicines to lower blood sugar (insulin, oral anti-diabetic medicines). Risk of hypoglycaemia (low blood sugar level), especially at the beginning of the treatment and in patients with impaired kidney function.
- lithium (used for the treatment of mania or depression). You should not take Zestan together with lithium. Nonetheless, if this combination is necessary, the level of lithium in the blood has to be monitored carefully. The concomitant therapy of Zestan and thiazides (a diuretic medicine) may increase the risk of interactions.

The use of the following medicines together with Zestan may increase the risk of side effects. These include kidney failure, changes in the number of blood cells, hyperkalaemia (high level of potassium in the blood):
- potassium supplements (including salt substitutes), potassium-sparing diuretics and other medicines that can increase the amount of potassium in your blood (e.g. trimethoprim and co-trimoxazole for infections caused by bacteria; ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots).
- The use of medicines including injectable gold (e.g. to treat rheumatism or joint disease) concomitantly with Zestan may increase the risk of a so called nitritoid reaction (dilatation of the blood vessels) with symptoms including flushing, feeling sick, dizziness and a fall in blood pressure, which can be very severe

- Medicines which are most often used to avoid rejection of transplanted organs (sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See section "Warnings and precautions".

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 Zestan" and "Warnings and precautions")

Zestan with food
The intake of food does not affect the take-up of lisinopril. Therefore you can take Zestan with or without food, but try to take it at the same time each day.

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 Zestan before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Zestan. Zestan 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.

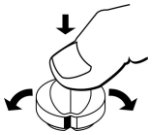
Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Zestan is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines
Your tablets are unlikely to affect your performance when driving or operating machinery. However, occasionally they may make you feel dizzy or tired especially when you first started taking Zestan. Do not drive or operate machines until you are sure that you are not affected.

3. How to take Zestan

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
You can take Zestan with or without food. Swallow the tablet with a glass of water in a single daily dose. Try to take the tablet at the same time each day. You should continue to take Zestan for as long as your doctor tells you.

For Zestan 2.5 mg / 5 mg tablets
If you have been told by your doctor to take ½ tablet, you will need to break the tablet along the 'score' line before taking by placing it on a hard surface with the centre groove facing upwards. Exert pressure from the top with your thumb and the tablet will break into two equal pieces (see picture).



For Zestan 10 mg / 20 mg tablets
If you have been told by your doctor to take ½ or ¼ tablet, you will need to break the tablet along the 'score' lines before taking by placing it on a hard surface with the centre groove facing upwards. Exert pressure from the top with your thumb and the tablet will break into four equal pieces (see picture).

The recommended dose depends on the severity of your disease and your individual patient profile.

The following recommended doses are given below:

For high blood pressure
Zestan may be used alone or together with other blood pressure reducing medicines.

The normal starting dose is 10 mg once a day. The dose will be increased gradually in intervals of at least 2–4 weeks until your blood pressure is being controlled effectively.
The usual long-term dose is 20 mg taken once a day. Depending on the response to your treatment, the dose might be gradually increased to the maximum dose of 80 mg once a day.

If you are already taking water tablets, your doctor will ask you to stop this diuretic treatment 2 to 3 days before you begin to take Zestan. If diuretic treatment cannot be stopped, lisinopril treatment should be started with 5 mg once a day. The following dose will be adjusted according to your blood pressure response. The diuretic treatment may be resumed.

If you have kidney problems you may be started on a lower dose. Your doctor decides about the dosage on the severity of your kidney disease. He/She will monitor you carefully especially in the beginning of the therapy (see section "Warnings and precautions; Kidney diseases").

<u>Use in children and adolescents (6-16 years)</u>
The dose is decided by your doctor. The recommended usual starting dose is 2.5 mg once daily if the child's weight is between 20 and 50 kg, 5 mg once a day if the child is weighing more than 50 kg. Your doctor will adjust the daily dose individually to a maximum of 20 mg daily in children weighing between 20 and 50 kg, and 40 mg in children weighing more than 50 kg. Doses above 40 mg are not recommended in children.
If your child has kidney problems, your doctor may set a lower starting dose or increase the dose gradually over a longer period.

For heart failure
Zestan should be used as adjunctive to another therapy to treat heart failures (e.g. with water tablets, digitalis, beta-blockers).

The normal starting dose is 2.5 mg once a day, which should be taken under medical supervision. The dose will then be increased in steps of not more than 10 mg in intervals of at least 2 weeks to control the symptoms of heart failure.

A maximum dose of 35 mg daily should not be exceeded.

Your doctor may adjust your dose based on your clinical response.

Following a heart attack
After receiving the recommended standard treatment (e.g. with thrombolytics, beta-blockers) the normal starting dose is

- 5 mg within 24 hours after the heart attack.
- Then 5 mg should be taken 24 hours after the first intake.

- After that 10 mg should be taken 48 hours after the first intake, followed by 10 mg once a day.

The usual maintenance dose is 10 mg once a day.

Your doctor may reduce the dose if you suffer from low blood pressure or from kidney disease.

The treatment should be continued for 6 weeks.

For problems related to diabetes
The normal starting dose is 10 mg once a day in hypertensive patients.

The dose can be increased to 20mg once a day, if necessary.

If you have kidney problems your dose may need to be adjusted.

Use in children
This medicine should not be used in children younger than 6 years or in children with severe kidney problems. Ask your doctor for advice.

Use in older people
Older people with normal kidney functions may take the same dosage as normal.

Use in patients with a kidney transplant
The use of Zestan is not recommended in patients who received a kidney transplant.

If you take more Zestan than you should
If you have taken too many tablets, contact your doctor or nearest hospital casualty department immediately for advice.

The symptoms of overdosage include low blood pressure (hypotension), circulatory shock, disturbances of the electrolyte balance (such as low levels of potassium, chloride and sodium in the blood), kidney failure, overbreathing (hyperventilation), fast heart beat (tachycardia), feeling the heart beat (palpitations), lower heart rate (bradycardia), dizziness, anxiety and cough.

If you forget to take Zestan
If you miss a dose of Zestan, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten dose. If you are at all concerned about this you should consult your doctor or pharmacist.

If you stop taking Zestan
Do not interrupt or stop treatment with Zestan without consulting your doctor.

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.

With the first one or two doses of these tablets, you may feel light-headed or faint due to the lowering of your blood pressure. This is usually stopped by lying down.

<u>You should STOP taking Zestan and tell your doctor immediately if you</u>
- begin to get itchy or develop serious skin reactions
- experience wheeziness or difficulty breathing or swallowing

- develop swelling of the hands, feet or ankles, face, lips, tongue or throat, or
- experience yellowing of the skin or whites of the eyes.

Common (may affect up to 1 in 10 people):
- dizziness
- headache
- orthostatic effects (including hypotension; in this case a fall in blood pressure on standing up which causes dizziness, light-headedness or fainting)
- cough
- diarrhoea
- vomiting
- disturbance of the kidney function (renal dysfunction)

Uncommon (may affect up to 1 in 100 people):
- swelling of the face, extremities, lips, tongue, glottis, and/or larynx (throat). These are symptoms of a hypersensitivity (allergic) angioneurotic oedema (see section "Warnings and precautions; Hypersensitivity (allergic) reactions or angioedema").
- mood alterations
- tingling or numbness in the hands or feet (paraesthesia)
- a feeling of dizziness or "spinning" (vertigo)
- taste disturbance
- sleep disturbances
- heart attack (myocardial infarction) or stroke (cerebrovascular accident), possibly secondary to excessive low blood pressure (hypotension) in high risk patients (see section "Warnings and precautions; Symptomatic hypotension (low blood pressure)")
- feeling your heartbeat (palpitations)
- faster heartbeat (tachycardia)
- poor blood circulation which makes the toes and fingers numb and pale (Raynaud's phenomenon)
- swelling and irritation inside the nose (rhinitis)
- feeling sick (nausea)
- abdominal pain
- indigestion
- rash
- itching (pruritus)
- impotence
- tiredness (fatigue)
- feeling of weakness (asthenia)
- increases in blood urea
- increases in serum creatinine
- increases in liver enzymes
- high levels of blood potassium which can cause abnormal heart rhythm (hyperkalaemia)

Rare (may affect up to 1 in 1,000 people):
- decreases in haemoglobin (red blood cells)
- decreases in haematocrit (proportion of red blood cells in blood)
- mental confusion
- dry mouth
- hives (urticaria)
- hair loss (alopecia)

- a skin disease which causes red patches and inflammation of the skin (psoriasis)
- a toxic condition caused by kidney failure and characterised by accumulation of urea in the blood (uraemia)
- acute renal failure
- breast growth in men (gynaecomastia)
- increases in serum bilirubin
- low blood levels of sodium which can cause muscle weakness, twitching or abnormal heart rhythm (hyponatraemia)
- increase of a certain hormone which regulates the amount of water in the blood and thus affects the electrolyte balance, e.g. decreased sodium levels, a condition called "syndrome of inappropriate antidiuretic hormone secretion" (SIADH) – the symptoms may be confusion, weakness, tiredness, headache, feeling sick (nausea), being sick (vomiting) and cramps

Very rare (may affect up to 1 in 10,000 people):
- when the bone marrow cannot produce enough blood cells (bone marrow depression)
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia, haemolytic anaemia)
- reduction in red platelets which increases risk of bleeding or bruising (thrombocytopenia)
- low number of white blood cells (leucopenia)
- low number of a certain type of white blood cells called neutrophil granulocytes (neutropenia)
- severe reduction in number of white blood cells which makes infections more likely (agranulocytosis; see section "Warnings and precautions; Alteration in the number of blood cells")
- enlargement of the lymph nodes (lymphadenopathy)
- autoimmune disease
- low blood sugar level (hypoglycaemia)
- difficulty in breathing or wheezing (bronchospasm)
- inflammation of the cavities of the nose (sinusitis)
- inflammation of the alveoli of the lungs caused by allergy (allergic alveolitis)
- accumulation of white blood cells (eosinophils) in the lungs (eosinophilic pneumonia)
- inflammation of the pancreas which causes severe pain in the abdomen and back (pancreatitis)
- swelling of the mucosa of the gut (intestinal angioedema)
- inflammation of the liver (hepatitis) – either hepatocellular or cholestatic
- yellowing of the skin or whites of the eyes caused by liver or blood problems and liver failure (jaundice; see section "Warnings and precautions; Liver diseases")
- increased sweating
- an autoimmune disease which causes blistering and raw sores on the skin (pemphigus)
- serious illness with blistering of the skin (toxic epidermal necrolysis)
- serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson Syndrome)
- a skin condition with itchy pink-red blotches (erythema multiforme)
- decreased/absent production of urine (oliguria/anuria)
- cutaneous pseudolymphoma (inflammatory response that results in an accumulation of inflammatory cells).

Not known (frequency cannot be estimated from the available data):
- depressive symptoms
- fainting (syncope).

A symptom complex has been reported which may include one or more of the following: fever, inflammation of blood vessels, often with skin rash (vasculitis), muscle pain (myalgia), joint pain (arthralgia)/ inflammation of the joints (arthritis), a positive antinuclear antibodies (ANA) (a blood test

to detect autoimmune diseases), elevated red blood cell sedimentation rate (ESR) (a sign of inflammation in the body, detected by a blood test), a type of white blood cells (eosinophilia) and high number of white blood cells (leucocytosis), rash, sensitivity to sunlight (photosensitivity) or other skin reactions (dermatological manifestations) may occur.

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 Zestan

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

Zestan 2.5 mg tablets: Do not store above 25°C
Zestan 5 mg/10 mg/20 mg tablets: Do not store above 30°C
Do not use this medicine after the expiry date which is stated on the outer packaging and the blister. The expiry date refers to the last day of that month. Return all unused medicines to your pharmacist for safe disposal.

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.

6. Contents of the pack and other information

What Zestan contains
The active substance is lisinopril (as dihydrate).

1 tablet contains 2.5 mg, 5 mg, 10 mg or 20 mg lisinopril.

The other ingredients are: Calcium hydrogen phosphate dihydrate, silica colloidal anhydrous, magnesium stearate, maize starch, mannitol, pregelatinised maize starch.

What Zestan looks like and contents of the pack
Zestan 2.5 mg Tablets
White, round, biconvex tablets scored on both sides and printed with '2.5' on one side. Each tablet contains 2.72 mg lisinopril dihydrate equivalent to 2.5 mg lisinopril.

Zestan 5 mg Tablets
White, round, biconvex tablets scored on both sides and printed with '5' on one side. Each tablet contains 5.44 mg lisinopril dihydrate equivalent to 5 mg lisinopril.

Zestan 10 mg Tablets
White, round, biconvex tablets quadrisected on both sides and printed with '10' on one side. Each tablet contains 10.89 mg lisinopril dihydrate equivalent to 10 mg lisinopril.

Zestan 20 mg Tablets
White, round, biconvex tablets quadrisected on both sides and printed with '20' on one side. Each tablet contains 21.78 mg lisinopril dihydrate equivalent to 20 mg lisinopril.

The tablets are packed in blisters of the following pack sizes
Zestan 2.5 mg tablets: 14, 20, 28, 30, 50, 56, 100 tablets.
Zestan 5 mg/10 mg/20 mg tablets: 14, 20, 28, 30, 50, 56, 60, 98, 100, 150, 200, 250, 300, 400, 500 &

1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing authorisation holder:
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary.

Manufacturer:
STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany.

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

- Austria	Lisinostad 5 mg/10 mg/20 mg
- Belgium	Lisinopril EG 5 mg/20 mg
- Denmark	Cardiostad 2.5 mg/5 mg/10 mg/20 mg
- Finland	Cardiostad 2.5 mg/5 mg/10 mg/20 mg tabletti
- Germany	Lisinopril STADA 2.5 mg/5 mg/10 mg/20 mg Tabletten
- Ireland	Zestan 2.5 mg/5 mg/10 mg/20 mg
- Italy	Lisinopril EG 5 mg/20 mg
- Luxembourg	Lisinopril EG 5 mg/20 mg
- Portugal	Lisinopril Ciclum 5 mg/20 mg
- Sweden	Lisinopril Stada 2.5 mg/5 mg/10 mg/20 mg
- The Netherlands	Lisinopril CF 5 mg/10 mg/20 mg

This leaflet was last revised in June 2019.