

Zestril® 5mg Tablets/ Zestril® 20mg Tablets

Patient Information Leaflet (continued)

- Children and adolescents (6 to 16 years old) with high blood pressure**
- * Zestril 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 usual starting dose is 2.5 mg once a day.
 - * For children who weigh more than 50 kg, the usual starting dose is 5 mg once a day.

If you take more Zestril than you should
If you take more Zestril than prescribed by your doctor, talk to a doctor or go to a hospital immediately. The following effects are most likely to happen: Dizziness, palpitations.

- If you forget to take Zestril**
- * 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 a forgotten dose.

If you stop taking Zestril
Do not stop taking your tablets, even if you are feeling 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, Zestril can cause side effects although not everybody gets them.

- If you experience any of the following reactions, **stop taking Zestril and see your doctor immediately:**
- * Severe allergic reactions (rare, affects 1 to 10 users in 10,000). 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 (very rare, affects less than 1 user in 10,000).
 - * 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 (very rare, affects less than 1 user in 10,000).

Other possible side effects:

- Common (affects 1 to 10 users in 100)**
- * 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 (affects 1 to 10 users in 1,000)**
- * 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.
 - * Spinning feeling (vertigo).
 - * Having difficulty sleeping.
 - * Stroke.
 - * Fast heart beat.
 - * Runny nose.
 - * Feeling sick (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.

- Rare (affects 1 to 10 users in 10,000)**
- * 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 Zestril 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 (affect less than 1 user in 10,000)**
- * Sinusitis (a feeling of pain and fullness behind your cheeks and eyes).
 - * Wheezing.
 - * Low levels of sugar in your blood (hypoglycaemia). The signs may include 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 available data)**
- * Symptoms of depression.
 - * Fainting.

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

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 How to store Zestril

- * Keep out of the reach and sight of children.
- * Do not use after the expiry date (EXP) which is stated on the blister strip and the carton. The expiry date refers to the last day of that month.
- * Zestril 5 mg and 20 mg Tablets: Do not store above 30°C.
- * Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

6 Further Information

What Zestril contains
The active substance is lisinopril (as dihydrate).
The other ingredients are mannitol, calcium hydrogen phosphate dihydrate, maize starch, pregelatinised starch and magnesium stearate. In addition, the pink and brownish-red tablets contain red iron oxide (E172).
Zestril is supplied in 2 strengths containing 5 mg or 20 mg of lisinopril (as dihydrate).

What Zestril looks like and contents of the pack
Zestril 5 mg Tablets: round, pink, uncoated, biconvex tablet with “♥ 5” on one side and bisected on the other side. Diameter 6 mm.
The tablet can be divided into equal halves.
Zestril 20 mg Tablets: round, brownish-red, uncoated, biconvex tablet with “♥ 20” on one side and plain on the other side. Diameter 8 mm.

Zestril tablets are available in aluminium foil blister packs of 28 tablets.

Parallel Product Authorisation Holder:
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Tel: + (0) 1527 505414 for help.