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Lizinna  
250 microgram/  
35 microgram  
Tablets

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Lizinna 250 microgram/35 microgram Tablets

Norgestimate/ethinylestradiol

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

Important things to know about combined hormonal contraceptives (CHCs):

- They are one of the most reliable reversible methods of contraception if used correctly
- They slightly increase the risk of having a blood clot in the veins and arteries, especially in the first year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks
- Please be alert and see your doctor if you think you may have symptoms of a blood clot (see section 2 "Blood clots")

What is in this leaflet:

- What Lizinna is and what it is used for
- What you need to know before you take Lizinna
- How to take Lizinna
- Possible side effects
- How to store Lizinna
- Contents of the pack and other information

1. WHAT LIZINNA IS AND WHAT IT IS USED FOR

Lizinna is a combined oral contraceptive pill. It is used to prevent pregnancy. Lizinna needs to be taken as directed to prevent pregnancy.

This contraceptive contains two types of female sex hormones, oestrogen and progestogen. Because it contains two hormones, Lizinna is called a 'combined hormonal contraceptive'.

These hormones prevent an egg being released from your ovaries so you cannot get pregnant. Also, Lizinna makes the fluid (mucus) in your cervix thicker which makes it more difficult for sperm to enter the womb.

Lizinna is a 21-day Pill - you take one tablet each day for 21 days, followed by 7 days when you take no pills.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LIZINNA

General notes

Before you start using Lizinna you should read the information on blood clots in section 2. It is particularly important to read the symptoms of a blood clot - see Section 2 "Blood clots".

It is important that you understand the benefits and risks of taking Lizinna before you start taking it, or when deciding whether to carry on taking it. Although Lizinna is suitable for most healthy women it is not suitable for everyone.

Tell your doctor if you have any of the illnesses or risk factors mentioned in this leaflet.

When you should not use Lizinna:

You should not use Lizinna if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor. Your doctor will discuss with you what other form of birth control would be more appropriate.

Do not take Lizinna

- If you are allergic to norgestimate, ethinylestradiol or any of the other ingredients in this medicine (listed in Section 6);
- if you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs;
- if you have ever had a heart attack or a stroke;
- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA - temporary stroke symptoms);
- if you are breast feeding and your baby is less than 6 weeks old;
- if you have an illness which runs in your family which affects fat levels in your blood (called dyslipoproteinaemia);
- if you know you have a disorder affecting your blood clotting (for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies);
- if you have ever been told you might have breast cancer or cancer of the womb, cervix or vagina;
- if you have unexplained vaginal bleeding;
- if you need an operation or if you are off your feet for a long time (see section 'Blood clots');
- if you have an irregular heartbeat (atrial fibrillation), problems with heart valves or heart failure;
- if you have (or have ever had) a type of migraine called 'migraine with aura';
- if you smoke 15 or more cigarettes a day and you are 35 years of age or older;
- if you have or have recently had a severe liver disease;
- if you have breast or liver cancer;
- if you have (or have ever had) an inflammation of the pancreas (pancreatitis);
- if your period has not yet started (girls in puberty);
- if you have any of the following diseases that may increase your risk of a clot in the arteries:
  - severe diabetes with blood vessel damage
  - very high blood pressure
  - a very high level of fat in the blood (cholesterol or triglycerides)
  - a condition known as hyperhomocysteinaemia

Medical check-ups

Before using Lizinna you will need to see your doctor for a medical check-up. Your doctor will ask about you and your family's medical problems and check your blood pressure. You may also need other checks, such as a breast examination but only if these are necessary for you or if you have any special concerns.

- You will need regular check-ups with your doctor or family planning nurse, usually when you need another prescription of Lizinna.
- You should go for regular cervical smear tests.
- Check your breasts and nipples every month for changes - tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.
- If you need a blood test tell your doctor that you are taking Lizinna, because it can affect the results of some tests.
- If you're going to have an operation, make sure your doctor knows about it. You may need to stop taking Lizinna about 4-6 weeks before the operation. This is to reduce the risk of a blood clot. Your doctor will tell you when you can start taking Lizinna again.

Warnings and precautions

When should you contact your doctor?

Seek urgent medical attention

- if you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke (see 'Blood clot' (thrombosis) section below.

For a description of the symptoms of these serious side effects please go to "How to recognise a blood clot".

Check with your doctor or pharmacist before using Lizinna if you have any of the following or they happen or get worse while using Lizinna and as you get older:

- if you are seriously overweight (you weigh 90 kg, which is 14 stone 2 lb) or more;
- if you smoke;
- if you or any of your close family have had blood clots;
- you have high blood pressure or your blood pressure gets higher;
- if you need an operation, or you are off your feet for a long time (see in section 2 'Blood clots');
- if you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas);
- if you have an irregular heartbeat (atrial fibrillation), problems with heart valves or heart failure, or if you or someone in your close family has had a heart attack or stroke at a young age;
- if you have a blood problem called porphyria;
- if you have systemic lupus erythematosus (SLE - a disease affecting your natural defence system);
- if you have haemolytic uraemic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys);
- if you have a hearing loss;
- if you have diabetes;
- if you have gallstones;
- if you have liver problems including yellowing of the skin and whites of the eye (jaundice);
- if you have a problem of the nervous system involving sudden movements of the body called 'Sydenham's chorea';
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- if you had a skin rash with blisters during pregnancy (called 'herpes gestationis');
- if you have 'pregnancy spots'. These are yellowish-brown patches or spots, especially on your face (called 'chloasma');
- if you are depressed;
- if a close relative has or has ever had breast cancer;
- if you have epilepsy;
- if you have hereditary angioedema, products containing oestrogens may cause or worsen the symptoms. **See your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or pharynx and/or difficulty swallowing or hives together with difficulty breathing.**
- if you suffer from migraines;
- if you have sickle cell anaemia (an inherited disease of the red blood cells);
- If you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- If you have varicose veins;
- if you think you might be pregnant;
- if you have just given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking Lizinna.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Lizinna.

Other medicines and Lizinna

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

Certain medicines and herbal remedies may stop Lizinna from working properly. If this happens you could get pregnant.

Tell your doctor if you are taking:

- medicines for HIV infection (such as ritonavir, nevirapine)
- medicines for infection called antibiotics (such as rifampicin and griseofulvin)
- medicines for epilepsy (such as topiramate, phenytoin sodium, carbamazepine, primidone, oxcarbamazepine and felbamate)
- medicine for high blood pressure in the blood vessels in the lungs (bosentan)
- medicine for excessive daytime sleepiness (modafinil)
- medicine for relaxation and difficulty in sleeping (sedatives such as barbiturates)
- St. John's Wort - a herbal remedy used for depression.

Lizinna can also affect other medicines- for example:

- ciclosporin (to prevent transplant rejection and for rheumatoid arthritis or some skin problems)
- lamotrigine (for epilepsy)
- prednisolone (a steroid to reduce inflammation)
- theophylline (for asthma, bronchitis and emphysema)

Talk to your doctor before taking Lizinna if you are taking any of these medicines. Your doctor may have to change how much of these medicines you are taking.

Risks of using combined hormonal contraceptives

The following information is based on information about combined birth control tablets. As Lizinna contains similar hormones to those used in combined birth control tablets, it is likely to have the same risks. All combined birth control tablets have risks, which may lead to disability or death.

Blood clots

Using a combined hormonal contraceptive such as Lizinna increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block blood vessels and cause serious problems.

Blood clots can develop

- in veins (referred to as a 'venous thrombosis', 'venous thromboembolism' or VTE)
- in the arteries (referred to as an 'arterial thrombosis', 'arterial thromboembolism' or ATE).

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, they may be fatal.

It is important to remember that the overall risk of a harmful blood clot due to Lizinna is small.

How to recognise a blood clot

Seek urgent medical attention if you notice any of the following signs or symptoms.

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none"><li>swelling of one leg or along a vein in the leg or foot especially when accompanied by:</li><li>pain or tenderness in the leg which may be felt only when standing or walking;</li><li>increased warmth in the affected leg;</li><li>change in colour of the skin on the leg e.g. turning pale, red or blue.</li></ul>	Deep vein thrombosis
<ul style="list-style-type: none"><li>sudden unexplained breathlessness or rapid breathing;</li><li>sudden cough without an obvious cause, which may bring up blood;</li><li>sharp chest pain which may increase with deep breathing;</li><li>severe light headedness or dizziness;</li><li>rapid or irregular heartbeat;</li><li>severe pain in your stomach;</li></ul>	Pulmonary embolism
If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a 'common cold').	

Symptoms most commonly occur in one eye:	Retinal vein thrombosis (blood clot in the eye)
<ul style="list-style-type: none"><li>immediate loss of vision or</li><li>painless blurring of vision which can progress to loss of vision.</li></ul>	Heart attack
<ul style="list-style-type: none"><li>chest pain, discomfort, pressure, heaviness</li><li>sensation of squeezing or fullness in the chest, arm or below the breastbone;</li><li>fullness, indigestion or choking feeling;</li><li>upper body discomfort radiating to the back, jaw, throat, arm and stomach;</li><li>sweating, nausea, vomiting or dizziness;</li><li>extreme weakness, anxiety, or shortness of breath;</li><li>rapid or irregular heartbeats.</li></ul>	Stroke
<ul style="list-style-type: none"><li>sudden weakness or numbness of the face, arm or leg, especially on one side of the body;</li><li>sudden confusion, trouble speaking or understanding;</li><li>sudden trouble seeing in one or both eyes;</li><li>sudden trouble walking, dizziness, loss of balance or coordination;</li><li>sudden, severe or prolonged headache with no known cause;</li><li>loss of consciousness or fainting with or without seizure.</li></ul> Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.	Blood clots blocking other blood vessels
<ul style="list-style-type: none"><li>swelling and slight blue discolouration of an extremity;</li><li>severe pain in your stomach (acute abdomen).</li></ul>	

Blood clots in a vein

What can happen if a blood clot forms in a vein?

- The use of combined hormonal contraceptives has been connected with an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare. Most frequently, they occur in the first year of use of a combined hormonal contraceptive.
- If a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung it can cause a pulmonary embolism.
- Very rarely a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

When is the risk of developing a blood clot in a vein highest?

The risk of developing a blood clot in a vein is highest during the first year of taking a combined hormonal contraceptive for the first time. The risk may also be higher if you restart taking a combined hormonal contraceptive (the same product or a different product) after a break of 4 weeks or more.

After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive.

When you stop Lizinna your risk of a blood clot returns to normal within a few weeks.

What is the risk of developing a blood clot?

The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you are taking. The overall risk of a blood clot in the leg or lung (DVT or PE) with Lizinna is small.

- Out of 10,000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains levonorgestrel or norethisterone, or norgestimate such as Lizinna, about 5-7 will develop a blood clot in a year.
- The risk of having a blood clot will vary according to your personal medical history (see "Factors that increase your risk of a blood clot" below)

	Risk of developing a blood clot in a year
Women who are <b>not using</b> a combined hormonal pill/patch/ring and are not pregnant	About 2 out of 10,000 women
Women using a combined hormonal contraceptive pill containing <b>levonorgestrel, norethisterone or norgestimate</b>	About 5-7 out of 10,000 women
Women using Lizinna	About 5-7 out of 10,000 women

Factors that increase your risk of a blood clot in a vein

The risk of a blood clot with Lizinna is small but some conditions will increase the risk. Your risk is higher:

- if you are very overweight (body mass index or BMI over 30kg/m2);
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50). In this case you could have a hereditary blood clotting disorder;
- if you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of Lizinna may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Lizinna ask your doctor when you can start using it again;
- as you get older (particularly above about 35 years);
- if you gave birth less than a few weeks ago.

The risk of developing a blood clot increases the more conditions you have.

Air travel (>4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.

It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that Lizinna needs to be stopped.

If any of the above conditions change while you are using Lizinna, for example a close family member experiences a thrombosis for no known reason, or you gain a lot of weight, tell your doctor.

Blood clots in an artery

What can happen if a blood clot forms in an artery?

Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

Factors that increase your risk of a blood clot in an artery

It is important to note that the risk of a heart attack or stroke from using Lizinna is very small but can increase:

- with increasing age (beyond about 35 years);
- if you smoke.** When using a combined hormonal contraceptive like Lizinna you are advised to stop smoking. If you are unable to stop smoking and are older than 35 your doctor may advise you to use a different type of contraceptive;
- if you are overweight;
- if you have high blood pressure;
- if a member of your immediate family has had a heart attack or stroke at a young age (less than about 50). In this case you could also have a higher risk of having a heart attack or stroke;
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides);
- if you get migraines, especially migraines with aura;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation);
- if you have diabetes.



