Non Printing Area	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
Non Printing Area	<ul> <li>This medicine has been prescribed for you only. Do not pass it on to others, it may harm them, even it their signs of illness are the same as yours.</li> <li>If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed it this leaflet.</li> </ul> Important things to know about combined hormonal contraceptives (CHCs):
	<ul> <li>They are one of the most reliable reversible methods of contraception if used correctly</li> <li>They slightly increase the risk of having a blood clot in the veins and arteries, especially in the first year or whe restarting a combined hormonal contraceptive following a break of 4 or more weeks</li> <li>Please be alert and see your doctor if you think you may have symptoms of a blood clot (see section 2 "Blood clots")</li> </ul>
Non Printing Area	What is in this leaflet: 1. What Lizinna is and what it is used for 2. What you need to know before you take Lizinna 3. How to take Lizinna 4. Possible side effects 5. How to store Lizinna 6. 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
Non Printing Area	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'.
Non Printing Area	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
Lizinna	General notes
250 microgram/	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").
35 microgram	It is important that you understand the benefits and risks of taking Lizinna before you start taking it, or when decidin whether to carry on taking it. Although Lizinna is suitable for most healthy women it is not suitable for everyone.
Tablets	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 mor appropriate.
	<ul> <li>Do not take Lizinna</li> <li>If you are allergic to norgestimate, ethinylestradiol or any of the other ingredients in this medicine (listed in Section 6)</li> <li>if you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lung (pulmonary embolus, PE) or other organs;</li> <li>if you have ever had a heart attack or a stroke;</li> <li>if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of</li> </ul>
Non Printing Area	<ul> <li>heart attack) or transient ischaemic attack (TIA- temporary stroke symptoms);</li> <li>if you are breast feeding and your baby is less than 6 weeks old;</li> <li>if you have an illness which runs in your family which affects fat levels in your blood (called dyslipoproteinemia);</li> <li>if you know you have a disorder affecting your blood clotting for instance, protein C deficiency, protein S deficienc antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies;</li> <li>if you have ever been told you might have breast cancer or cancer of the womb, cervix or vagina;</li> <li>if you have unexplained vaginal bleeding;</li> <li>if you need an operation or if you are off your feet for a long time (see section 'Blood clots');</li> <li>if you have an irregular heartbeat (atrial fibrillation), problems with heart valves or heart failure;</li> <li>if you have (or have ever had) a type of migraine called 'migraine with aura';</li> <li>if you smoke 15 or more cigarettes a day and you are 35 years of age or older;</li> <li>if you have or have recently had a severe liver disease;</li> </ul>
Non Printing Area	<ul> <li>if you have breast or liver cancer;</li> <li>if you have (or have ever had) an inflammation of the pancreas (pancreatitis);</li> <li>if your period has not yet started (girls in puberty);</li> <li>if you have any of the following diseases that may increase your risk of a clot in the arteries:</li> <li>severe diabetes with blood vessel damage</li> <li>very high blood pressure</li> <li>a very high level of fat in the blood (cholesterol or triglycerides)</li> <li>a condition known as hyperhomocysteinaemia</li> </ul>
Non Printing Area	<ul> <li>Medical check-ups</li> <li>Before using Lizinna you will need to see your doctor for a medical check-up. Your doctor will ask about you and you family's medical problems and check your blood pressure. You may also need other checks, such as a breat examination but only if these are necessary for you or if you have any special concerns.</li> <li>You will need regular check-ups with your doctor or family planning nurse, usually when you need another prescription of Lizinna.</li> <li>You should go for regular cervical smear tests.</li> <li>Check your breasts and nipples every month for changes - tell your doctor if you can see or feel anything odd, such a lumps or dimpling of the skin.</li> <li>If you need a blood test tell your doctor that you are taking Lizinna, because it can affect the results of some tests.</li> <li>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 stataking Lizinna again.</li> </ul>

Warnings and precautions

Seek urgent medical attention

Non Printing Area

When should you contact your doctor?

• 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

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

thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke (see '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 a blood problem called porphyria;  if you have heamolytic uraemic syndrome (HUS - a disease affecting your natural defence system);  if you have heamolytic uraemic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys);  if you have a hearing loss;  if you have gallstones;  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 have 'pregnancy spots'. These are yellowish-brown patches or spots, especially on your face (called 'chloasma');  if you have departed;  if you are depressed;  if a close relative has or has ever had breast cancer;	Symptoms most commonly occur in one eye:  immediate loss of vision or  painless blurring of vision which can progress to loss of vision.  chest pain, discomfort, pressure, heaviness  sensation of squeezing or fullness in the chest, arm or below the breastbone;  fullness, indigestion or choking feeling;  upper body discomfort radiating to the back, jaw, throat, arm and stomach;  sweating, nausea, vomiting or dizziness;  extreme weakness, anxiety, or shortness of breath;  rapid or irregular heartbeats.  sudden weakness or numbness of the face, arm or leg, especially on one side of the body;  sudden confusion, trouble speaking or understanding;  sudden trouble seeing in one or both eyes;  sudden, severe or prolonged headache with no known cause;  loss of consciousness or fainting with or without seizure.  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.  swelling and slight blue discolouration of an extremity;	Retinal vein thrombosis (bloclot in the eye)  Heart attack  Stroke
• if you have epilepsy;	severe pain in your stomach (acute abdomen)	Vessels

if you suffer from migraine;

If you have varicose veins;

Other medicines and Lizinna

Tell your doctor if you are taking:

lamotrigine (for epilepsy)

Blood clots can develop

How to recognise a blood clot

accompanied by:

Are you experiencing any of these signs?

increased warmth in the affected leg;

• severe light headedness or dizziness;

rapid or irregular heartbeat;

• severe pain in your stomach;

if you think you might be pregnant;

delivery you can start taking Lizinna.

 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

• if you have just given birth you are at an increased risk of blood clots. You should ask your doctor how soon after

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes

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

• medicines for epilepsy (such as topiramate, phenytoin sodium, carbamazepine, primidone, oxcarbamazepine and

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

The following information is based on information about combined birth control tablets. As Lizinna contains similar

Using a combined hormonal contraceptive such as Lizinna increases your risk of developing a blood clot compared with

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

What are you possibly suffering

Deep vein thrombosis

Pulmonary embolism

hormones to those used in combined birth control tablets, it is likely to have the same risks. All combined birth control

pharynx and/or difficulty swallowing or hives together with difficulty breathing.

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

• If you have an inflammation in the veins under the skin (superficial thrombophlebitis);

• if you have sickle cell anaemia (an inherited disease of the red blood cells);

medicines obtained without a prescription, including herbal medicines.

medicines for infection called antibiotics (such as rifampicin and griseofulvin)

medicine for high blood pressure in the blood vessels in the lungs (bosentan)

• medicine for relaxation and difficulty in sleeping (sedatives such as barbiturates)

• ciclosporin (to prevent transplant rejection and for rheumatoid arthritis or some skin problems)

not using one. In rare cases a blood clot can block blood vessels and cause serious problems.

in the arteries (referred to as an 'arterial thrombosis', 'arterial thromboembolism' or ATE).

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

• in veins (referred to as a 'venous thrombosis', 'venous thromboembolism' or VTE)

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

• swelling of one leg or along a vein in the leg or foot especially when

• change in colour of the skin on the leg e.g. turning pale, red or blue.

• sudden cough without an obvious cause, which may bring up blood;

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

• sudden unexplained breathlessness or rapid breathing;

as a respiratory tract infection (e.g. a 'common cold').

• sharp chest pain which may increase with deep breathing;

pain or tenderness in the leg which may be felt only when standing or

• medicines for HIV infection (such as ritonavir, nevirapine)

medicine for excessive daytime sleepiness (modafinil)

• St. John's Wort - a herbal remedy used for depression.

Lizinna can also affect other medicines- for example:

prednisolone (a steroid to reduce inflammation)

much of these medicines you are taking.

theophylline (for asthma, bronchitis and emphysema)

Risks of using combined hormonal contraceptives

tablets have risks, which may lead to disability or death.

## Blood clots in a vein

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

severe pain in your stomach (acute abdomen).

 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.

vessels

• 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

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) Bick of developing a blood clot in a

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

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

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.

If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot

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

## Combined hormonal contraceptives and cancer

Breast cancer has been found more often in women who take combined hormonal contraceptives. However, it is possible that the combined hormonal contraceptive is not the cause of more women having breast cancer. It may be that women taking the combined hormonal contraceptive are examined more often. This might mean that there is a better chance of the breast cancer being noticed. The increased risk gradually goes down after stopping the combined hormonal contraceptive. After 10 years, the risk is the same as for people who have never used the combined hormonal contraceptive.

Cervical cancer

Cervical cancer also has been found more often in women taking combined hormonal contraceptives. However, this may be due to other causes. These include more sexual partners and sexually transmitted disease.

In rare cases, liver tumours which are not cancer have been found in women taking combined hormonal contraceptives. Even more rarely, liver tumours which are cancer have been found. This can cause bleeding inside the body with very bad pain in the stomach area.

If this happens to you, talk to your doctor immediately.

Taking Lizinna with food, drink and alcohol

It is not expected that food or drink will affect the way Lizinna works.

Pregnancy and breast-feeding Do not start taking Lizinna if you are pregnant. If you think you might be pregnant while taking Lizinna, do a pregnancy test to confirm that you are before you stop taking your tablets.

If you are breast-feeding, your doctor or nurse may advise you not to take Lizinna and advise you on alternative contraception. Taking this medicine while breast-feeding may not stop you from becoming pregnant.

Driving and using machines

Lizinna has no known effect on the ability to drive or use machines.

Sexually transmitted disease

Lizinna will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to

Lizinna contains Lactose: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using this medicine.

. HOW TO TAKE LIZINNA

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you

Take Lizinna every day for 21 days

Lizinna comes in a strip of 21 tablets, each marked with a day of the week. Take your tablet at the same time every day. Start by taking a tablet marked with the correct day of the week.

Follow the direction of the arrows on the strip. Take one tablet each day. Swallow each tablet whole, with water if necessary. Do not chew the tablet.

not have finished when it is time to start your next strip of tablets.

Then have seven tablet-free days After you have taken all 21 tablets in the strip, you have seven days when you take no tablets. So if you take the last

tablet of one pack on a Friday, you will take the first tablet of your next pack on the Saturday of the following week. Within a few days of taking the last tablet from the strip, you should have a withdrawal bleed like a period. This bleed may

You don't need to use extra contraception during these seven tablet-free days as long as you have taken your tablets correctly and start the next strip of tablets on time.

Then start your next strip Start taking your next strip of Lizinna after the seven tablet-free days even if you are still bleeding. Always start the new

As long as you take Lizinna correctly, you will always start each new strip on the same day of the week.

If you have not used a contraceptive with hormones in the previous month

Begin with Lizinna on the first day of the cycle (that is the first day of your period). If you start Lizinna on the first day of your period you are immediately protected against pregnancy. You may also begin on day 2-5 of the cycle, but then you must use extra protective measures (for example, a condom) for the first 7 days.

Changing from a combination hormonal contraceptive, or combination contraceptive vaginal ring or patch You can start Lizinna preferably on the day after the last active tablet (the last tablet containing active substances) of your previous pill, but at the latest on the day after the tablet-free days of your previous pill (or after the last inactive tablet

of your previous pill). When changing from a combination contraceptive vaginal ring or patch, follow the advice of your Changing from a progestogen-only-method (progestogen-only pill, injection, implant or a progestogen-

releasing IUD) You may switch any day from the progestogen-only pill (from an implant or an IUD on the day of its removal, from an injectable when the next injection would be due) but in all of these cases use extra protective measures (for example, a condom) for the first 7 days of tablet-taking.

After a miscarriage Follow the advice of your doctor.

your next period.

You can start Lizinna between 21 and 28 days after having a baby, If you start later than day 28, use a so-called barrier method (for example, a condom) during the first seven days of Lizinna use. If, after having a baby, you have had sex before starting Lizinna (again), be sure that you are not pregnant or wait until

If you are breast-feeding and want to start Lizinna (again) after having a baby

Read the section on "Breast-feeding".

Ask your doctor what to do if you are not sure when to start.

## If you are **more than 12 hours** late taking a tablet, the protection against pregnancy may be reduced. The greater the Do not take a double dose to make up for a forgotten dose. number of tablets that you have forgotten, the greater is the risk of becoming pregnant. The risk of incomplete protection against pregnancy is greatest if you forget a tablet at the beginning or at the end of the Lizinna should not be used by girls in puberty that have not had their first period yet. strip. Therefore, you should keep to the following rules (see the diagram). If you have further questions on the use of this medicine, ask your doctor, pharmacist or nurse. More than one tablet forgotten in this strip Contact your doctor. Like all medicines, this medicine can cause side effects, although not everybody gets them. Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be Continue taking the tablets at the usual time and use extra precautions for the next 7 days, for example, a condom. If you due to Lizinna, please talk to your doctor. have had sex in the week before forgetting the tablet you may be pregnant. In that case, contact your doctor. An increased risk of blood clots in your veins (venous thromboembolism (VTE)) or blood clots in your arteries (arterial One tablet forgotten in week 2 thromboembolism (ATE)) is present for all women taking combined hormonal contraceptives. For more detailed Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. information on the different risks from taking combined hormonal contraceptives please see section 2 "What you need to Continue taking the tablets at the usual time. The protection against pregnancy is not reduced, and you do not need to know before you use Lizinna". take extra precautions. One tablet forgotten in week 3 Tell your doctor, pharmacist or nurse if you are worried about any side effects which you think may be due to Lizinna. This includes any side effects not listed in this leaflet. You can choose between two possibilities: 1. Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. Instead of taking the tablet-free period start the next strip. Very common: may affect more than 1 in 10 people Most likely, you will have a period at the end of the second strip but you may have light or menstruation-like bleeding • Headache (but if severe, unusual or long lasting, see a doctor as soon as possible) during the second strip. Upset stomach 2. You can also stop the strip and go directly to the tablet-free period of 7 days (record the day on which you forgot Nausea your tablet). If you want to start a new strip on the day you always start, make the tablet-free period less than 7 days. Vomiting Diarrhoea If you follow one of these two recommendations, you will remain protected against pregnancy. Vaginal bleeding If you have forgotten any of the tablets in a strip, and you do not have a bleeding during the first tablet-free period, you Bleeding and spotting between your periods for the first few months may be pregnant. Contact your doctor before you start the next strip. Painful or unusual periods Common: may affect up to 1 in 10 people More than 1 tablet Ask your doctor for advice Urinary tract infections (pain on passing urine) forgotten in 1 strip Vaginal infections such as thrush yes Allergic reactions (hypersensitivity) Fluid retention Depression → Had sex in the previous week before forgetting? Mood changes Feeling nervous Feeling dizzy Difficulty sleeping (insomnia) • Migraine (see a doctor as soon as possible if this is your first migraine or it's worse than usual) •Take the forgotten tablet Stomach ache •Use a barrier method (condom) for the following Bloating 7 days and Constipation •Finish the strip Passing wind Acne Only 1 tablet Rash •Take the forgotten tablet (taken more than 12 in week 2 Muscle spasms •Finish the strip hours late) Pain in the legs and arms Back-ache Vaginal discharge •Take the forgotten tablet and No menstrual bleeding (periods) •Finish the strip Painful breasts •Instead of the gap week start the next strip Chest pain Swollen hands, ankles or feet Feeling weak in week 3 Weight gain Stop the strip immediately Uncommon: may affect up to 1 in 100 people •Begin the gap week (not longer than 7 days, Abnormal cells in the cervix (identified by a smear test) including the forgotten tablet Changes in appetite Then start the next strip Weight may vary Feeling anxious If you start a new strip of tablets late, or make your 'week off' longer than eight days, you may not be protected from Change in sex drive pregnancy. If you had sex in the last seven days, ask your doctor, nurse or pharmacist for advice. You may need to Feeling faint consider emergency contraception. You should also use extra contraception, such as a condom, for seven days. Having a tingling sensation or numbness Changes in vision If you lose a tablet Dry eyes If you lose a tablet, just take a tablet from a spare strip. Then take all the other tablets from your current strip as usual. You Feeling your heart beat (palpitations) can then keep the opened spare strip in case you lose any more tablets. Creation of blood clots (thrombosis) High blood pressure What to do in the case of vomiting or severe diarrhoea Hot flushes If you vomit within 3-4 hours after taking a tablet or you have severe diarrhoea, there is a risk that the active substances Sudden chest pain, difficulty breathing in the pill will not be fully taken up by your body. The situation is almost the same as forgetting a tablet. After vomiting or Hair thinning (alopecia) diarrhoea, take another tablet from a reserve strip as soon as possible. If possible take it within 12 hours of when you Excessive hair growth (hirsutism) normally take your pill. If that is not possible or 12 hours have passed, you should follow the advice given under "If you Hives (urticaria) forget to take Lizinna". Itchiness of the skin Redness of the skin If you have absence of bleeding Changes in skin colour Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you Muscle pain have taken your tablets correctly. Start your next strip at the normal time. If you think that you might have put yourself at Breast problems, such as: risk of pregnancy (for example, by missing tablets or taking other medicines), or if you miss a second bleed, you should fuller breasts do a pregnancy test. producing fluid from the nipples If you are pregnant, stop taking Lizinna and see your doctor. • Ovarian cysts (may cause pain and swelling of the abdomen, changes in periods) Vaginal dryness If you take more Lizinna than you should Weight loss It is unlikely that taking more than one tablet will do you any harm, but you may feel sick, vomit or have some vaginal

If you forget to take Lizinna

If you are **less than 12 hours** late taking a tablet, the protection against pregnancy is not reduced. Take the tablet as

soon as you remember and then take the following tablets again at the usual time.

bleeding. Talk to your doctor if you have any of these symptoms.

not cause you or the baby any harm if you get pregnant straight away.

break. Tablet taking should then continue as usual.

If you want to delay having a period, finish the strip of tablets you are taking. Start the next strip the next day without a

When you use the second strip, you may have some unexpected bleeding or spotting on the days that you take the

If you are planning a baby, it is best to use another method of contraception after stopping Lizinna until you have had a

proper period. Your doctor relies on the date of your last natural period to tell you when your baby is due. However, it will

medicine, but do not worry. Take the next strip after the usual 7 day break even if you are still bleeding or spotting.

If you want to delay a period

in a lung (i.e. PE) heart attack mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA) blood clots in the liver, stomach/intestine, kidneys or eye. The chance of having a blood clot may be higher if you have any other conditions that increase this risk (See section 2 for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot) Not known: frequency cannot be estimated from the available data Benign liver tumors Breast tumours Signs of breast cancer include: dimpling of the skin changes in the nipple any lumps you can see or feel. • Changes in fat levels in the blood (seen by blood tests) Contact lenses may feel uncomfortable • Serious allergic reaction that causes swelling of the face and throat (angioedema) Red nodules or lumps that are usually seen on both shins (erythema nodosum) Night sweats Reduced amount of breast milk (if breast feeding) Tell your doctor, pharmacist or nurse if any existing conditions get worse while you are taking Lizinna. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in 5. HOW TO STORE LIZINNA Keep this medicine out of the sight and reach of children. Do not use Lizinna after the expiry date shown on the strip. The expiry date refers to the last day of that month. Store in the original package to protect from light. Do not throw away any medicines via wastewater. 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 Lizinna contains • Each tablet contains: 250 micrograms of the progestogen Norgestimate, and 35 micrograms of the oestrogen Ethinylestradiol. The other ingredients are Lactose Anhydrous, Lactose, Monohydrate, Povidone K-25, dl-a-tocopherol, Microcrystalline cellulose, Croscarmellose sodium, Starch Pregelatinised (starch 1500), Magnesium Stearate, Indigo carmine aluminium lake What Lizinna looks like and the contents of the pack Lizinna tablets are round, blue, uncoated flat beveled edge tablets with '146' debossed on one side and plain on the other side, with a diameter of 6.4mm. They are supplied in packs containing: 21, 63, 126 tablets. Not all pack sizes may be marketed. **Marketing Authorisation Holder** Morningside Healthcare Limited 115 Narborough Road Manufacturer Morningside Pharmaceuticals Ltd 5 Pavilion Way, Castle Business Park Loughborough, Leicestershire LE115GW This leaflet was last revised in March 2014

Harmful blood clots in a vein or artery for example:

in a leg or foot (i.e. DVT)

Stroke

Leicester

LE3 0PA

UK

You may get irregular, little or no bleeding. This usually happens in the first 3 months and especially if your periods were

not regular before you started using Lizinna.

Rare: may affect up to 1 in 1000 people

 Inflammation of the liver (hepatitis) Signs of severe liver problems include: severe pain in your upper abdomen

yellow skin or eyes (jaundice)

• Inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis)

Fluctuation in your appetite

 Feeling dizzy or spinning Faster heart beat

Increased sweating

 Sensitivity to light Vaginal discharge

Lumpy breasts

Loss of sex drive