

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.
 If you are **more than 12 hours** late taking a tablet, the protection against pregnancy may be reduced. The greater the 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 strip. Therefore, you should keep to the following rules (see the diagram).

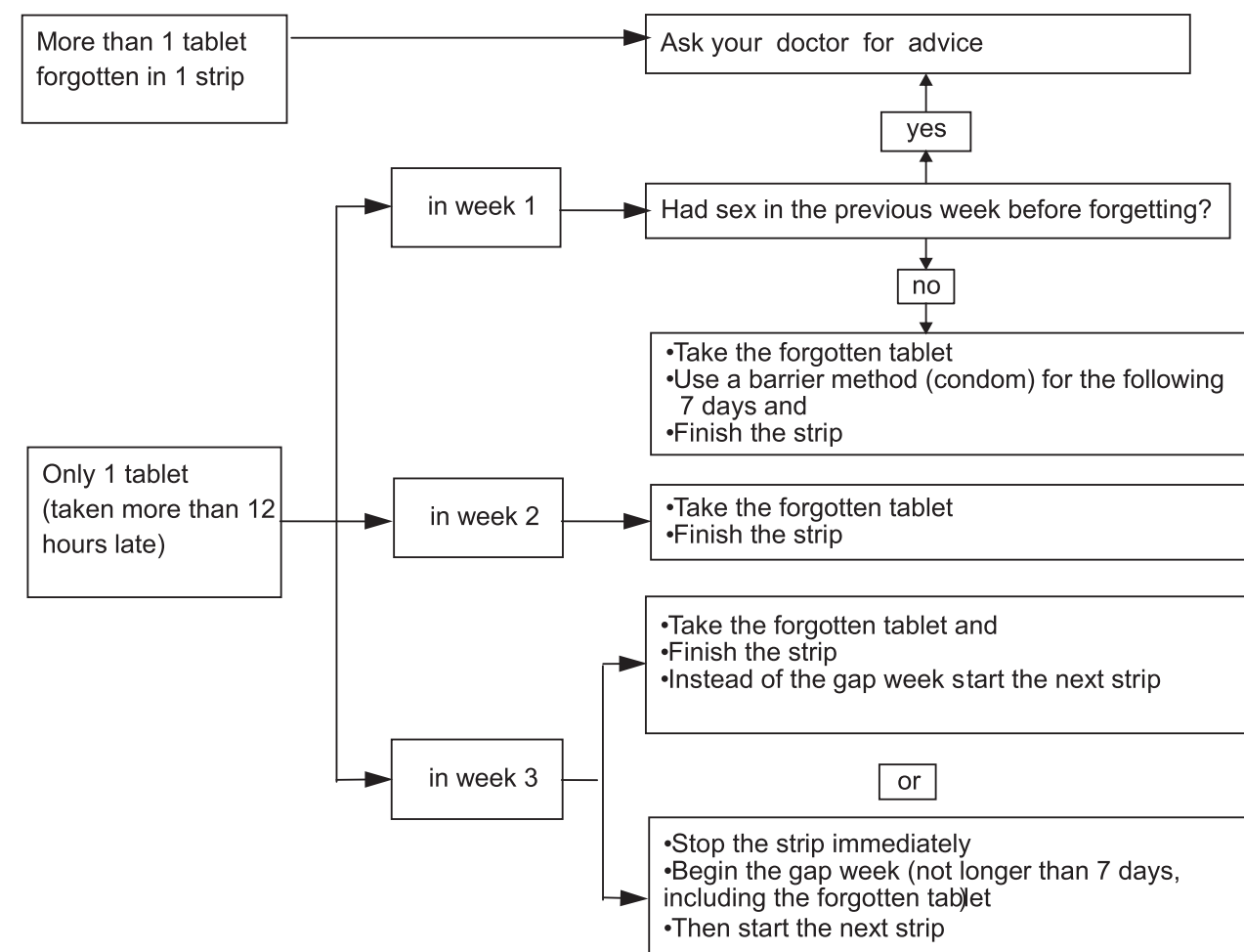
More than one tablet forgotten in this strip
 Contact your doctor.

One tablet forgotten in week 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 and use extra precautions for the next 7 days, for example, a condom. If you have had sex in the week before forgetting the tablet you may be pregnant. In that case, contact your doctor.

One tablet forgotten in week 2
 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. The protection against pregnancy is not reduced, and you do not need to take extra precautions.

One tablet forgotten in week 3
 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. Most likely, you will have a period at the end of the second strip but you may have light or menstruation-like bleeding during the second strip.
 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 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.

If you follow one of these two recommendations, you will remain protected against pregnancy.
 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 may be pregnant. Contact your doctor before you start the next strip.



If you start a new strip of tablets late, or make your 'week off' longer than eight days, you may not be protected from pregnancy. If you had sex in the last seven days, ask your doctor, nurse or pharmacist for advice. You may need to consider emergency contraception. You should also use extra contraception, such as a condom, for seven days.

If you lose a tablet
 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 can then keep the opened spare strip in case you lose any more tablets.

What to do in the case of vomiting or severe diarrhoea
 If you vomit within 3-4 hours after taking a tablet or you have severe diarrhoea, there is a risk that the active substances 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 diarrhoea, take another tablet from a reserve strip as soon as possible. If possible take it *within 12 hours* of when you normally take your pill. If that is not possible or 12 hours have passed, you should follow the advice given under 'If you forget to take Lizinna'.

If you have absence of bleeding
 Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you have taken your tablets correctly. Start your next strip at the normal time. If you think that you might have put yourself at risk of pregnancy (for example, by missing tablets or taking other medicines), or if you miss a second bleed, you should do a pregnancy test.
 If you are pregnant, stop taking Lizinna and see your doctor.

If you take more Lizinna than you should
 It is unlikely that taking more than one tablet will do you any harm, but you may feel sick, vomit or have some vaginal bleeding. Talk to your doctor if you have any of these symptoms.

If you want to delay a period
 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 break. Tablet taking should then continue as usual.

When you use the second strip, you may have some unexpected bleeding or spotting on the days that you take the 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 get pregnant
 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 not cause you or the baby any harm if you get pregnant straight away.

If you stop taking Lizinna
 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.
 Do not take a double dose to make up for a forgotten dose.

Use in children and adolescent
 Lizinna should not be used by girls in puberty that have not had their first period yet.

If you have further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
 If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be due to Lizinna, please talk to your doctor.

An increased risk of blood clots in your veins (venous thromboembolism (VTE)) or blood clots in your arteries (arterial thromboembolism (ATE)) is present for all women taking combined hormonal contraceptives. For more detailed information on the different risks from taking combined hormonal contraceptives please see section 2 'What you need to know before you use Lizinna'.

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.

Very common; may affect more than 1 in 10 people
 • Headache (**but if severe, unusual or long lasting, see a doctor as soon as possible**)
 • Upset stomach
 • Nausea
 • Vomiting
 • Diarrhoea
 • Vaginal bleeding
 • Bleeding and spotting between your periods for the first few months
 • Painful or unusual periods

Common; may affect up to 1 in 10 people
 • Urinary tract infections (pain on passing urine)
 • Vaginal infections such as thrush
 • Allergic reactions (hypersensitivity)
 • Fluid retention
 • Depression
 • 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**)
 • Stomach ache
 • Bloating
 • Constipation
 • Passing wind
 • Acne
 • Rash
 • Muscle spasms
 • Pain in the legs and arms
 • Back-ache
 • Vaginal discharge
 • No menstrual bleeding (periods)
 • Painful breasts
 • Chest pain
 • Swollen hands, ankles or feet
 • Feeling weak
 • Weight gain

Uncommon; may affect up to 1 in 100 people
 • Abnormal cells in the cervix (identified by a smear test)
 • Changes in appetite
 • Weight may vary
 • Feeling anxious
 • Change in sex drive
 • Feeling faint
 • Having a tingling sensation or numbness
 • Changes in vision
 • Dry eyes
 • Feeling your heart beat (palpitations)
 • Creation of blood clots (thrombosis)
 • High blood pressure
 • Hot flushes
 • Sudden chest pain, difficulty breathing
 • Hair thinning (alopecia)
 • Excessive hair growth (hirsutism)
 • Hives (urticaria)
 • Itchiness of the skin
 • Redness of the skin
 • Changes in skin colour
 • Muscle pain
 • Breast problems, such as:
 • fuller breasts
 • producing fluid from the nipples
 • Ovarian cysts (may cause pain and swelling of the abdomen, changes in periods)
 • Vaginal dryness
 • Weight loss

Rare; may affect up to 1 in 1000 people
 • Lumpy breasts
 • Fluctuation in your appetite
 • Loss of sex drive
 • Feeling dizzy or spinning
 • Faster heart beat
 • Inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis)
 • Inflammation of the liver (hepatitis)
 • Signs of severe liver problems include:
 • severe pain in your upper abdomen
 • yellow skin or eyes (jaundice)
 • Increased sweating
 • Sensitivity to light
 • Vaginal discharge

• Harmful blood clots in a vein or artery for example:
 • in a leg or foot (i.e. DVT)
 • in a lung (i.e. PE)
 • heart attack
 • stroke
 • 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 tumours
 • 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)
 • Stroke
 • Fit
 • 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 this leaflet.

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, di-a-tocopherol, Microcrystalline cellulose, Croscarmellose sodium, Starch Pregelatinised (starch 1500), Magnesium Stearate, Indigo carmine aluminium lake (E 132).

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.

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Non Printing Area