

Package leaflet: Information for the user

Elvina 0.03mg/3mg film-coated tablets

ethinylestradiol and drospirenone

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”).

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.
- If you get any side effect, 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 Elvina is and what it is used for
2. What you need to know before you use Elvina
3. How to take Elvina
4. Possible side effects
5. How to store Elvina
6. Contents of the pack and other information

1. What Elvina is and what it is used for

- Elvina is a contraceptive pill and is used to prevent pregnancy.
- Each tablet contains a small amount of two different female hormones, namely drospirenone and ethinylestradiol.
- Contraceptive pills that contain two hormones are called “combination” pills.

2. What you need to know before you use Elvina

General notes

Before you start using Elvina 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”.

Before you can begin taking Elvina, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure and, depending upon your personal situation, may also carry out some other tests.

In this leaflet, several situations are described where you should stop using Elvina, or where the reliability of Elvina may be decreased. In such situations you should either not have sex or you should take extra non-hormonal contraceptive precautions, e.g. use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because Elvina alters the monthly changes of body temperature and cervical mucus.

Elvina, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

Do not use Elvina

You should not use Elvina 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.

- if you are allergic to ethinylestradiol or drospirenone, or any of the other ingredients of this medicine (listed in section 6.). This may cause itching, rash or swelling.
- 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 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 need an operation or if you are off your feet for a long time (see section ‘Blood clots’).
- 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 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
- if you have (or have ever had) a type of migraine called ‘migraine with aura’.
- if you have (or have ever had) a liver disease and your liver function is still not normal.
- if your kidneys are not working well (renal failure).
- if you have (or have ever had) a tumour in the liver.
- if you have (or have ever had) or if you are suspected of having breast cancer or cancer of the genital organs.
- if you have any unexplained bleeding from the vagina.
- Elvina contains soya lecithin. If you are allergic to peanut or soya, do not use this medicinal product.

Do not use Elvina if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see also in section Other medicines and Elvina).

Children and adolescents

Elvina is not intended for use in females whose periods have not yet started

Warnings and precautions

Talk to your doctor or pharmacist before taking Elvina

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 clots’ section below).

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

Tell your doctor if any of the following conditions apply to you.

In some situations you need to take special care while using Elvina or any other combination pill, and your doctor may need to examine you regularly. If any of the following conditions applies to you, tell your doctor before starting to use Elvina. If the condition develops, or gets worse while you are using Elvina, you should also tell your doctor.

If you have:

- if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Products containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema.
- a close relative who has ever had breast cancer;
- a disease of the liver or the gallbladder;
- diabetes;
- depression or mood changes;
- epilepsy (see “Other medicines and Elvina”);
- a disease that first appeared during pregnancy or earlier use of sex hormones (for example, hearing loss, a blood disease called porphyria, yellowing of the skin or eyes (jaundice), itching of the whole body (pruritus), skin rash with blisters during pregnancy (gestational herpes), (a nerve disease causing sudden movements of the body (Sydenham’s chorea) ;
- ever had a discolouration of the skin especially on the face or neck known as “pregnancy patches” (chloasma). If so, avoid direct sunlight or ultraviolet light.
- Crohn’s disease or ulcerative colitis (chronic inflammatory bowel disease);
- systemic lupus erythematosus (SLE - a disease affecting your natural defence system);
- haemolytic uraemic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys);
- sickle cell anaemia (an inherited disease of the red blood cells);
- 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 need an operation, or you are off your feet for a long time (see in section 2 ‘Blood clots’);
- 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 Elvina;
- an inflammation in the veins under the skin (superficial thrombophlebitis);
- varicose veins.

BLOOD CLOTS

Using a combined hormonal contraceptive such as Elvina 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 Elvina 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?
- swelling of one leg or along a vein in the leg or foot especially when accompanied by:	Deep vein thrombosis

<ul style="list-style-type: none"> - pain or tenderness in the leg which may be felt only when standing or walking - increased warmth in the affected leg - change in colour of the skin on the leg e.g. turning pale, red or blue 	
<ul style="list-style-type: none"> - sudden unexplained breathlessness or rapid breathing; - sudden cough without an obvious cause, which may bring up blood; - sharp chest pain which may increase with deep breathing; - severe light headedness or dizziness; - rapid or irregular heartbeat - severe pain in your stomach; <p>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').</p>	Pulmonary embolism
<p>Symptoms most commonly occur in one eye:</p> <ul style="list-style-type: none"> - immediate loss of vision or - painless blurring of vision which can progress to loss of vision 	Retinal vein thrombosis (blood clot in the eye)
<ul style="list-style-type: none"> - 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 	Heart attack
<ul style="list-style-type: none"> - 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 trouble walking, dizziness, loss of balance or coordination; - sudden, severe or prolonged headache with no known cause; - loss of consciousness or fainting with or without seizure. <p>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.</p>	Stroke
<ul style="list-style-type: none"> - swelling and slight blue discolouration of an extremity; - severe pain in your stomach (acute abdomen) 	Blood clots blocking other blood vessels

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 Elvina 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 Elvina 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, norethisterone, or norgestimate about 5-7 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains drospirenone such as Elvina between about 9 and 12 women 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 not using 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 levonorgestrel, norethisterone or norgestimate	About 5-7 out of 10,000 women
Women using Elvina	About 9-12 out of 10,000 women

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

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

- if you are very overweight (body mass index or BMI over 30 kg/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 Elvina may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Elvina 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 Elvina needs to be stopped.

If any of the above conditions change while you are using Elvina, 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 Elvina is very small but can increase:

- with increasing age (beyond about 35 years);
- **if you smoke.** When using a combined hormonal contraceptive like Elvina 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 may be increased even more.

If any of the above conditions change while you are using Elvina, 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.

Elvina and cancer

Breast cancer has been observed slightly more often in women using combination pills, but it is not known whether this is caused by the treatment. For example it may be that more tumours are detected in women on combination pills because they are examined by their doctor more often. The risk of breast tumours becomes gradually less after stopping the combination hormonal contraceptives. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in pill users. Contact your doctor if you have unusually severe abdominal pain.

Psychiatric disorders

Some women using hormonal contraceptives including Elvina have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Bleeding between periods

During the first few months that you are taking Elvina, you may have unexpected bleeding (bleeding outside the seven pill-free days). If this bleeding occurs for more than a few months, or if it begins after some months, contact your doctor as they must find out if anything is wrong.

What to do if no bleeding occurs during the seven pill-free days

If you have taken all the tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant.

If the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Only start the next strip if you are sure that you are not pregnant.

Other medicines and Elvina

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

Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you use Elvina. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long.

Do not use Elvina if you have Hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir, as these products may cause increases in liver function blood test results (increase in ALT liver enzyme).

Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicinal products.

Elvina can be restarted approximately 2 weeks after completion of this treatment. See section “Do not use Elvina”.

Some medicines can have an influence on the blood levels of Elvina and can make it less effective in preventing pregnancy or can cause unexpected bleeding. These include:

- medicines used for the treatment of
 - epilepsy (e.g. barbiturates, carbamazepine, phenytoin, primidon, felbamate, oxcarbazepine, topiramate),
 - tuberculosis (e.g. rifampicin),
 - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efavirenz),
 - high blood pressure in the blood vessels in the lungs (bosentan)
 - fungal infection (e.g. griseofulvin, ketoconazole),
 - the symptomatic treatment of arthrosis (etoricoxib),
- the herbal remedy St. John's wort (*Hypericum perforatum*). If you want to use herbal products containing St. John's wort while you are already using Elvina you should consult your doctor first.

Elvina may influence the effect of other medicines, e.g.

- ciclosporin (medicine used for the treatment of suppression of tissue rejection following transplant surgery),
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures),
- tizanidine (medicine used for the treatment of muscle spasticity),
- theophyllin (a medicine for the treatment of asthma).

Ask your doctor or pharmacist for advice before taking any medicine.

Taking Elvina with food and drink

Elvina may be taken with or without food, if necessary with a small amount of water.

Laboratory tests

If you need a blood test, tell your doctor or the laboratory staff that you are taking the pill, because hormonal contraceptives can affect the results of some tests.

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

If you are pregnant, you must not take Elvina. If you become pregnant while taking Elvina, you must stop taking it immediately and contact your doctor. If you want to become pregnant, you can stop taking Elvina at any time (see also “If you stop taking Elvina”).

Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

Use of Elvina is generally not advisable when a woman is breast-feeding. If you want to take the pill while you are breast-feeding you should contact your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

There is no information suggesting that use of Elvina affects driving or the use of machines.

Elvina contains lactose and soya lecithin

Elvina contains 48.17 mg lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Elvina also contains 0.070 mg soya lecithin. If you are allergic to peanut or soya, do not use this medicinal product.

3. How to take Elvina

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take Elvina every day for 21 days

Elvina comes in strips of 21 pills, each marked with a day of the week.

- Take your pill at the same time every day.
- Start by taking a pill marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 21 pills.
- Swallow each pill whole, with water if necessary. Do not chew the pill.

Then have seven pill-free days

After you have taken all 21 pills in the strip, you have seven days when you take no pills. So, if you take the last pill of one pack on a Friday, you will take the first pill of your next pack on the Saturday of the following week.

Within a few days of taking the last pill from the strip, you should have a withdrawal bleed like a period. This bleed may not have finished when it is time to start your next strip of pills.

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

Then start your next strip

Start taking your next strip of Elvina after the seven pill-free days – even if you are still bleeding.

Always start the new strip on time.

During the seven pill-free days, when you take no tablets, bleeding should begin (so-called withdrawal

bleeding). This usually starts on the 2nd or 3rd day after the last tablet of Elvina. Start the following strip after the last day of the seven pill-free days, whether your bleeding has stopped or not.

When can you start with the first strip?

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

Begin with Elvina on the first day of your cycle (that is the first day of your period). If you start Elvina 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 combined hormonal contraceptive, or combined contraceptive vaginal ring or patch.**

You can start Elvina preferably on the day after the last active tablet (the last tablet containing the active substances) of your previous pill, but at the latest on the day after the tablet-free days of your previous pill finish (or after the last inactive tablet of your previous pill).

When changing from a combined contraceptive vaginal ring or a transdermal patch, follow the advice of your doctor.

- **Changing from a progestogen-only-method (progestogen-only pill), injection, implant or a progestogen-releasing intrauterine system (IUS))**

You may switch any day from the progestogen-only pill (from an implant or an IUS 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 taking Elvina.

- **After a miscarriage or abortion**

If you have had a miscarriage or abortion during the first three months of pregnancy, your doctor may tell you to start taking Elvina straight away. This means that you will have contraceptive protection with your first pill.

- **After having a baby**

You can start taking Elvina 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 taking Elvina. If, after having a baby, you have had sex before starting Elvina (again), you must first be sure that you are not pregnant or wait until your next period.

- **If you are breast-feeding and want to start Elvina 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 take more Elvina than you should

There are no reports of serious harmful results of taking too many Elvina tablets.

If you take several tablets at once then you may feel sick or vomit or you may bleed from the vagina. Even girls who have not yet started to menstruate but have accidentally taken this medicine may experience such bleeding.

If you have taken too many Elvina tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

If you forget to take Elvina

- 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 also the diagram below):

- **More than one tablet forgotten in this strip**

Contact your doctor.

- **One tablet is 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 is 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. If you forget more than one tablet use an additional barrier method such as a condom for 7 days.

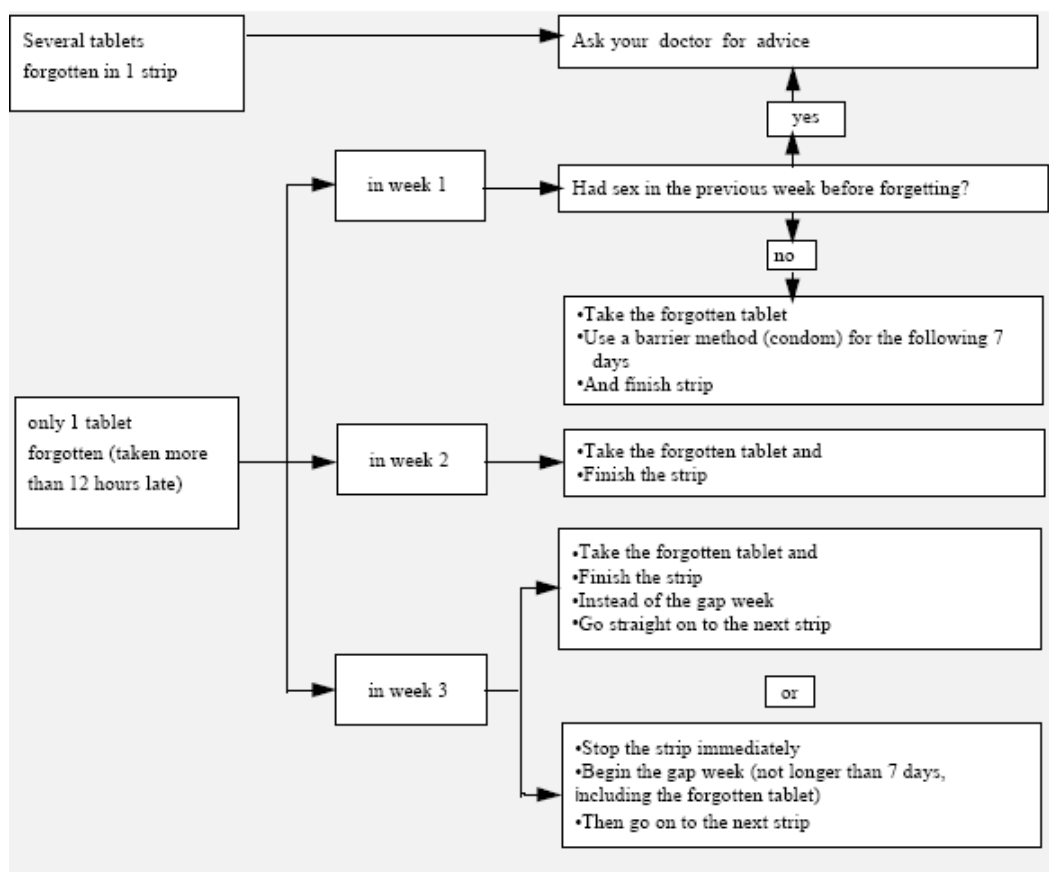
- **One tablet is forgotten in week 3**

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 having seven pill-free days start the next strip as soon as you have taken the last tablet. Most likely, you will have a period at the end of the second strip but you may also 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 (**record the day on which you forgot your tablet, so that the tablet-free period does not exceed the maximum of 7 days**). 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.



What to do in the case of vomiting or severe diarrhoea

If you vomit within 3-4 hours of 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 Elvina”.

Delaying your period: what you need to know

Although it is not recommended, you can delay your period by skipping the seven pill-free days and going straight to a new strip of Elvina and finishing it. You may experience light or menstruation-like bleeding while using this second strip. After the usual pill-free period of 7 days, *start your next strip*.

It is advisable to consult your doctor for advice before deciding to delay your menstrual period.

Changing the first day of your period: what you need to know

If you take the tablets according to the instructions, then your period will begin during the seven pill-free days. If you have to change this day, make the pill-free period shorter (but never longer – 7 days is the maximum!). For example, if you start the seven pill-free days on a Friday, and you want to change this to a Tuesday (3 days earlier) start a new strip 3 days earlier than usual. If you make the pill-free period very short (for example, 3 days or less) you may not have any bleeding during this time. You may then experience light or menstruation-like bleeding.

If you are not sure what to do, consult your doctor.

If you stop taking Elvina

You can stop taking Elvina whenever you want. If you do not want to become pregnant, ask your doctor for advice about other reliable methods of birth control.

If you want to become pregnant, stop taking Elvina and wait for a menstrual period before trying to become pregnant. You will be able to calculate the expected delivery date more easily.

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. 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 Elvina, please talk to your doctor.

Serious side effects

Contact a doctor immediately if you experience any of the following symptoms of angioedema: swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also section “Warnings and precautions”).

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 Elvina”.

The following is a list of the side effects that have been linked with the use of drospirone/ethinylestradiol:

Common side effects (may affect up to 1 in 10 people):

- depressive mood
- headache, migraine
- nausea
- menstrual disorders, bleeding between periods, breast pain, breast tenderness, thick whitish vaginal discharge, vaginal yeast infection

Uncommon side effects (may affect up to 1 in 100 people):

- changes interest in sex
- high blood pressure, low blood pressure
- vomiting, diarrhoea
- acne, severe itching, skin rash, hair loss (alopecia)
- breast enlargement, vaginal infection
- fluid retention, body weight changes

Rare side effects (may affect up to 1 in 1,000 people):

- allergic reactions (hypersensitivity)
- asthma
- hearing impairment
- the skin conditions erythema nodosum (characterized by painful reddish skin nodules), or erythema multiforme (characterized by rash with target-shaped reddening or sores)
- breast secretion
- 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).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance

Website: www.hpra.ie

5. How to store Elvina

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

Do not use this medicine after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.

Store below 30°C. Store in the original package in order to protect from light.

Do not throw away any medicine 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 Elvina contains

- The active substances are 0.03 mg ethinylestradiol and 3 mg drospirenone in each tablet.
- The other ingredients are:

Tablet core: lactose monohydrate, pregelatinised maize starch, maize starch, povidone K-25, magnesium stearate

Film-coating: polyvinyl alcohol, titanium dioxide (E171), talc (E553b), macrogol 3350, lecithin (soya)

What Elvina looks like and contents of the pack

White or almost white, round, biconvex film-coated tablet. Engraving on one side: "G63", other side is without engraving.

Elvina 0.03mg/3mg film-coated tablets are packaged PVC/PVDC//Al blister pack.

The blisters are packed into folding box with patient leaflet and etui storage bag is enclosed in each box.

Pack sizes:

21 film-coated tablets

3×21 film-coated tablets

6×21 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Gedeon Richter Plc.

1103 Budapest,

Gyömrői út 19-21

Hungary

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

Austria: Volina
Finland: Midiana
Ireland: Elvina
Hungary: Drospirenone/Ethinylestradiol Richter

This leaflet was last revised in June 2023.