

Flexyess PL

Package leaflet: Information for the user

Flexyess 0.02 mg / 3 mg film-coated tablets
Ethinylestradiol / Drospirenone

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 effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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").*

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1. What Flexyess is and what it is used for

- Flexyess 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 take Flexyess**General notes**

Before you start using Flexyess, 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 Flexyess, 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 Flexyess, or where the reliability of Flexyess 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 Flexyess alters the monthly changes of body temperature and of cervical mucus.

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

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When you should not use Flexyess

You should not use Flexyess 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 Flexyess

- 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 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) 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
- 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.

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 clots’ section below).

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

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

In some situations you need to take special care while using Flexyess or any other combination pill, and your doctor may need to examine you regularly. If the condition develops, or gets worse while you are using Flexyess, you should also tell your doctor.

- if a close relative has or has ever had breast cancer
- if you have a disease of the liver or the gallbladder
- if you have diabetes
- if you have depression
- if you have Crohn's disease ulcerative colitis (chronic inflammatory bowel disease)
- 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 sickle cell anaemia (an inherited disease of the red blood cells)
- 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 need an operation, or you are off your feet for a long time (see in section 2 'Blood clots');
- 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 Flexyess.
- If you have an inflammation in the veins under the skin (superficial thrombophlebitis).
- If you have varicose veins
- if you have epilepsy (see page x "Other medicines and Flexyess")
- if you have a disease that first appeared during pregnancy or earlier use of sex hormones (for example, hearing loss, a blood disease called porphyria, skin rash with blisters during pregnancy (gestational herpes), a nerve disease causing sudden movements of the body (Sydenham's chorea)
- If you have or have ever had golden brown pigment patches (chloasma), so called "pregnancy patches", especially on the face. If this is the case, avoid direct exposure to sunlight or ultraviolet light.
- if you have hereditary angioedema, products containing oestrogens may cause or worsen the symptoms. You should 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.

Blood clots

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

Blood clots can develop

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

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- 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 Flexyess 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: • 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	Deep vein thrombosis
• 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; 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’).	Pulmonary embolism
Symptoms most commonly occur in one eye: • immediate loss of vision or • painless blurring of vision which can progress to loss of vision	Retinal vein thrombosis (blood clot in the eye)
• 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;	Heart attack

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Are you experiencing any of these signs?	What are you possibly suffering from?
• 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 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. 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..	Stroke
• 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 Flexyess 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.

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The overall risk of a blood clot in the leg or lung (DVT or PE) with Flexyess 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 Flexyess, 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 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 Flexyess	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 Flexyess 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 (eg. 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 Flexyess may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Flexyess 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.

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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 Flexyess needs to be stopped.

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

- with increasing age (beyond about 35 years);
- **if you smoke.** When using a combined hormonal contraceptive like Flexyess, 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 Flexyess, 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.

Flexyess 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.

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The occurrence 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 contraceptive pill users. In isolated cases, these tumors have led to life-threatening internal bleeding. Contact your doctor if you have unusually severe abdominal pain.

Some studies suggest that long-term use of the pill increases a woman's risk of developing cervical cancer. However, it is not clear to what extent sexual behaviour or other factors such as Human Papilloma Virus (HPV) increases this risk.

Bleeding between periods

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

What to do if no bleeding occurs during the 4-day tablet-free interval

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. Continue to take Flexyess as usual.

If you have taken the tablets incorrectly, or, if you have taken tablets correctly but the expected bleeding does not happen twice in a row, you may be pregnant. Contact your doctor immediately.

Bleeding under treatment with Flexyess normally does not occur every 4 weeks but at reduced frequency with intervals of up to 120 days. Unexpected pregnancy may be difficult to recognize. If for some reason you think you may be pregnant, do a pregnancy test. If the test is positive, or you are still unsure contact your doctor.

Do not continue with tablet-taking until you are sure that you are not pregnant. In the meantime, use non-hormonal contraceptive measures. See also under 'Pregnancy'.

Other medicines and Flexyess

Always tell your doctor which medicines or herbal products you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you take Flexyess. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long, or, whether the use of another medicine you need must be changed.

Some medicines

- can have an influence on the blood levels of Flexyess
- can make it **less effective in preventing pregnancy**
- can cause unexpected bleeding.

These include

- medicines used for the treatment of
 - epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine)
 - 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)
 - fungal infections (e.g. griseofulvin, ketoconazole)
 - arthritis, arthrosis (etoricoxib)

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- high blood pressure in the blood vessels in the lungs (bosentan)
- the herbal remedy St. John's wort

Flexyess may **influence the effect** of other medicines, e.g.

- medicines containing ciclosporin
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures)
- theophylline (used to treat breathing problems)
- tizanidine (used to treat muscle pain and/or muscle cramps).

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

Flexyess with food and drink

Flexyess 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

If you are pregnant, you must not take Flexyess. If you become pregnant while taking Flexyess you must stop immediately and contact your doctor.

If you want to become pregnant, you can stop taking Flexyess at any time (see also 'If you want to stop taking Flexyess' on page X).

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

Breast-feeding

Use of Flexyess 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 Flexyess affects driving or use of machines.

Flexyess contains lactose

If you cannot tolerate certain sugars, contact your doctor before you take Flexyess.

3. How to take Flexyess

General advice

Always use Flexyess exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The Clyk tablet dispenser will guide you through the regimen.

Take one tablet of Flexyess every day, if necessary with a small amount of water. You may take the tablets with or without food, but you should take the tablets every day around the same time.

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Tablet intake**1) Mandatory phase (day 1-24):**

When starting Flexyess, tablets must be taken continuously for a minimum of 24 days, after which you can either:

- stop taking tablets for a 4-day tablet-free interval
- or continue taking them for up to 120 days (see flexible phase).

During the first 24 days the Clyk tablet dispenser does not allow a 4-day tablet-free interval.

2) Flexible phase (day 25-120):

During days 25-120, the tablets can be taken continuously up to a maximum of 120 days. Within this period, you may decide yourself when to take the 4-day tablet-free interval. This will usually cause bleeding.

During the flexible phase, the Clyk tablet dispenser allows you to initiate a 4-day tablet-free interval at any time.

If you do not initiate the 4-day tablet-free interval yourself, the Clyk dispenser automatically initiates a 4-day tablet-free interval after 120 days of continuous tablet intake.

In the event of continued bleeding (three consecutive days) during days 25-120, it is advisable to take the 4-day tablet-free interval. This will reduce the total number of days with bleeding.

Tablet-free interval

A tablet-free interval should never be longer than 4 days and it should only be started if tablet taking has been continuous for 24 days.

During the 4-day tablet-free interval bleeding usually occurs and may not have finished before you start the next tablet intake cycle.

After each 4-day tablet-free interval, you will start a new intake cycle of a minimum of 24 days to a maximum of 120 days. After the mandatory phase of 24 days of continuous tablet taking, you again may choose when to have the tablet-free 4 day interval between days 25 and 120.

Preparing the Clyk tablet dispenser for use

Flexyess can only be used in combination with the Clyk dispenser.

The separate document instructions for use of the Clyk dispenser should be carefully read before and during use.

1. Remove the OC dispenser from its package
2. Remove a cartridge (containing 30 tablets) from its blister immediately prior to insertion
3. Hold the dispenser in the palm of your hand so you see the viewing window for the tablets (see picture)
4. Hold the cartridge in your other hand so that you can see the tablets.
5. Insert the cartridge in the dispenser, pushing it in all the way and leave in. The tablets are now visible through the viewing window.

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6. Turn the dispenser over to view the display screen on the front. This now tells you that your OC dispenser is turned on and ready to use.



Replacing an empty cartridge with a new cartridge

When the cartridge is empty release it from the tablet dispenser by pressing the cartridge release button (the button with a blue circle on it). Only remove the new cartridge from its blister immediately prior to insertion.

Dispose of the empty cartridge and insert a new one as described above.

When can you start with Flexyess?

- *If you have not used a contraceptive with hormones in the previous month*
Begin with Flexyess on the first day of the cycle (that is, the first day of your period). If you start Flexyess 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 another combined hormonal contraceptive, or combined contraceptive vaginal ring or patch*
You can start Flexyess preferably on the day after the last tablet-free interval or after the last hormone-free tablet of your previous pill. When changing from a combined contraceptive vaginal ring or patch, follow the advice of your doctor.
- *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 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 tablet-taking.
- *After a miscarriage or abortion*
Follow the advice of your doctor.

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- *After having a baby*
You can start Flexyess between 21 and 28 days after having a baby. If you start later than day 28-you must use a so-called barrier method (for example, a condom) during the first seven days of Flexyess use.
If, after having a baby, you have had sex before starting Flexyess (again), you must first be sure that you are not pregnant or you must wait until your next period.
- *If you are breast-feeding and want to start Flexyess (again) after having a baby*
Read the section on “Breast-feeding” on page X.

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

If you take more Flexyess than you should

There are no reports of serious harmful results of taking too many Flexyess tablets. If you take several tablets at once then you may have symptoms of nausea or vomiting. Young girls may have bleeding from the vagina.

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

If you forget to take Flexyess

IMPORTANT: If you have missed one or more pills, check if the ‘Use an additional method of contraception’ symbol (an exclamation mark in a box) is displayed on your Clyk dispenser’s home screen.

Whenever the home screen displays the exclamation mark, you should use an additional non-hormonal method of contraception (e.g. condoms). You should use an additional method of non-hormonal contraception until the exclamation mark disappears.

Management of missed tablets

- If you are **less than 24 hours** late when taking a tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and then continue taking the tablets again at the usual time.
- If you are **more than 24 hours** late in taking any tablet your protection against pregnancy may be reduced. The following advice can be given in daily practice:
 - **More than one tablet forgotten**
Check if the ‘Use an additional method of contraception’ symbol (an exclamation mark in a box) is displayed on your Clyk dispenser’s home screen and follow the above instructions. If you are unsure what to do, ask your doctor for advice.
 - **1 tablet missed during Day 1-7**
You should take the last missed tablet as soon as you remember, even if this means taking two tablets at the same time. Then continue to take tablets at the usual time. In addition check if the ‘Use an additional method of contraception’ symbol (an exclamation mark in a box) is displayed on your Clyk dispenser’s home screen and follow the above instructions. If you have had sex in the week before forgetting the tablet you must realize that there is a risk of pregnancy. In that case, contact your doctor.
 - **1 tablet missed during Day 8-24**
You should take the last missed tablet as soon as you remember, even if this means taking two tablets at the same time. Then continue to take tablets at your usual time. If you have taken your tablets correctly in the 7 days preceding the first missed tablet, there is no need to use extra contraceptive

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precautions. However, if this is not the case or if you have missed more than 1 tablet, you should check if the ‘Use an additional method of contraception’ symbol (an exclamation mark in a box) is displayed on your Clyk dispenser’s home screen and follow the above instructions. If you are unsure what to do, ask your doctor for advice.

- **1 tablet missed during Day 25-120**

You may choose either of the following options, without the need for extra contraceptive precautions.

1. Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time until you have taken at least 7 tablets in a row without interruption.

or

2. Stop taking tablets, have a 4-day pill-free break (also count the day you missed your tablet) and continue with a new intake cycle of Flexyess

- If you have forgotten tablets, and you do not have a bleeding during your 4-day pill-free break, you may be pregnant. Contact your doctor before you continue to take the tablets, (see also section “*What to do if no bleeding occurs during the 4-day interval*”).

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 as soon as possible. If possible take it within 24 hours of when you normally take your pill. If this is not possible or 24 hours have passed, use extra protection (e.g. a condom) for the next 7 days.

If you stop taking Flexyess

You can stop taking Flexyess 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 Flexyess 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 Flexyess, 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 take Flexyess”.

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

Common side effects (affects 1 to 10 users in 100):

- mood swings, depression, decreased interest in or loss of interest in sex
- headache
- migraine

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- nausea
- breast pain, **problems with your periods, such as irregular periods, absence of periods**

Uncommon side effects (affects 1 to 10 users in 1,000)

- nervousness, sleepiness
- dizziness, ‘pins and needles’
- migraine, varicose veins, increased blood pressure
- stomach ache, vomiting, indigestion, intestinal gas, inflammation of the stomach, diarrhoea
- acne, itching, rash
- aches and pains, e.g. back pain, limb pain, muscle cramps
- vaginal fungal infection, pelvic pain, breast enlargement, benign breast lumps, uterine/vaginal bleeding (which usually subsides during continued treatment), genital discharge, hot flushes, inflammation of the vagina (vaginitis), problems with your periods, painful periods, reduced periods, very heavy periods, vaginal dryness, abnormal cervical smear
- lack of energy, increased sweating, fluid retention
- weight increase

Rare side effects (affects 1 to 10 users in 10,000):

- candida (fungal infection)
- anemia, increase in the number of platelets in the blood
- allergic reaction
- hormonal (endocrine) disorder
- increased appetite, loss of appetite, abnormally high concentration of potassium in the blood, abnormally low concentration of sodium in the blood
- failure to experience an orgasm, insomnia
- giddiness, tremor
- eye disorders, e.g. inflammation of the eyelid, dry eyes
- abnormally rapid heartbeat
- inflammation of a vein, nosebleed, fainting
- enlarged abdomen, bowel disorder, feeling bloated, stomach hernia, fungal infection of the mouth, constipation, dry mouth
- pain of bile ducts or the gallbladder, inflammation of the gallbladder
- yellow brown patches on the skin, eczema, hair loss, acne-like inflammation of the skin, dry skin, lumpy inflammation of the skin, excessive hair growth, skin disorder, stretch marks on the skin, skin inflammation, light-sensitive skin inflammation, skin nodules
- difficult or painful sex, inflammation of the vagina (vulvovaginitis), bleeding following intercourse, withdrawal bleeding, breast cyst, increased number of breast cells (hyperplasia), malignant lumps in the breast, abnormal growth on the mucosal surface of the neck of the womb, shrinkage or wasting of the lining of the womb, ovarian cysts, enlargement of the womb
- feeling generally unwell
- weight loss
- 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.

Flexyess PL

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).

The following side effects have also been reported, but their frequency cannot be estimated from the available data: hypersensitivity, erythema multiforme (rash with target-shaped reddening or sores).

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, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Flexyess

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

This medicinal product does not require any special storage conditions.

The tablet dispenser is not watertight and should always be kept dry.

Do not use this medicine after the expiry date which is stated on the folding box and the blister of the cartridge (see “EXP”). Once you have removed the cartridge from the blister, insert it immediately into the dispenser and take the tablets within 40 days.

Do not throw away any medicines 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. FURTHER INFORMATION

What Flexyess contains

- The active substances are ethinylestradiol (as betadex clathrate) and drospirenone. Each tablet contains 0.020 milligram ethinylestradiol (as betadex clathrate) and 3 milligram drospirenone.
- The other ingredients are
Tablet core: lactose monohydrate, maize starch, magnesium stearate (E470b),
Tablet film-coating: hypromellose (E464), talc (E553b), titanium dioxide (E171) and red iron oxide (E172).

What Flexyess looks like and contents of the pack

- The Flexyess tablet is light pink, round with convex surfaces; one side is embossed with the letters "DS" in a regular hexagon. The tablets are presented in a cartridge which is then packed in a blister.
- The Starter pack for Flexyess contains:
1 carton box with 1 blister containing 1 cartridge with 30 tablets and
1 carton box containing 1 dispenser.
- The refill packs for Flexyess contain 1, 3, 4 or 12 blisters, each containing a cartridge with 30 tablets

Marketing Authorisation Holder

Bayer Limited, The Atrium, Blackthorn Road, Dublin 18

Flexyess PL

In case of questions about the use of the tablet dispenser please contact the local BAYER subsidiary.

Manufacturer

Bayer Pharma AG
Berlin, Germany

and

Bayer Weimar GmbH and Co. KG
Weimar, Germany

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

Country	Name, strength, and pharmaceutical form
Austria (AT)	Flexyess 0,02 mg/3 mg Filmtabletten
Belgium (BE)	Yvidually 0,02 mg/3 mg, filmomhulde tabletten
Bulgaria (BG)	Flexyess 0,02 mg/3 mg филмирани таблетки
Czech Republic (CZ)	Flexyess 0,02 mg/ 3 mg potahované tablety
Estonia (EE)	Yvidually, 0,02 mg/ 3 mg õhukese polümeerikattega tabletid
Finland (FI)	Flexyess 0,02 mg/3 mg tabletti, kalvopäällysteinen
Germany (DE)	Flexyess 0,02 mg/3 mg Filmtabletten
Hungary (HU)	Flexyess 0,02 mg/3 mg filmtabletta
Ireland (IE)	Flexyess 0.02 mg/3 mg film-coated tablets
Italy (IT)	Yvidually 0,02 mg/3 mg compresse rivestite con film
Latvia (LV)	Yvidually 0,02 mg/3 mg apvalkotās tabletes
Lithuania (LT)	Flexyess 0,02 mg/3 mg plėvele dengtos tabletės
Luxembourg (LU)	Flexyess 0,02 mg/3 mg, comprimés pelliculés
Malta (MT)	Flexyess 0.02 mg / 3 mg film-coated tablets
The Netherlands (NL)	Yvidually 0,02 mg/3 mg, filmomhulde tabletten
Poland (PL)	Flexyess, 0,02 mg/3 mg, tabletki powlekane
Portugal (PT)	Flexyess 3 mg + 0,02 mg comprimido revestido por película
Romania (RO)	Yvidually 0,02 mg/3 mg, comprimate filmate
Slovak Republic (SK)	Flexyess, 0,02 mg/3 mg filmom obalená tableta
Slovenia (SI)	Flexyess 0,02 mg/ 3 mg filmsko obložene tablete
Spain (ES)	Flexyess 0,02 mg/ 3 mg comprimidos recubiertos con película
United Kingdom (UK)	Flexyess 0.02 mg / 3 mg film-coated tablets

This leaflet was last revised in August 2015