

Package leaflet: Information for the user

<invented name> 0.02 mg/3 mg film-coated tablets

Ethinylestradiol/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 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, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet:

1. What <invented name> is and what it is used for
2. What you need to know before you take <invented name>
3. How to take <invented name>
4. Possible side effects
5. How to store <invented name>
6. Contents of the pack and other information

1. What <INVENTED NAME>is and what it is used for

- <invented name> is a contraceptive pill and is used to prevent pregnancy.
- Each of the 24 tablets contain 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<INVENTED NAME>

Before you start using <invented name> for the first time you should discuss with your doctor how to use this product.

Before you start using <invented name> 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 <invented name>, 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 <invented name>, or where the reliability of <invented name> may be decreased. In such situations you should either not have sex or you should take extra non-hormonal contraceptive precautions, for example, use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable as <invented name>

alters the monthly changes of body temperature and of cervical mucus.

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

If you have any unusual symptoms such as unexplained pains in the chest, abdomen or legs you must consult your doctor immediately.

Do not take <invented name>

You should not use <invented name> if you have any of the conditions listed below. If you 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 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 (or 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 ischaemia 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 <invented name> (listed section 6.). This may cause itching, rash or swelling.
- If you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir (see also in section Other medicines and <Invented name>).

Warnings and precautions

When should you contact your doctor?

Seek urgent medical attention

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

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

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

If the condition develops, or gets worse while you are using [invented name], 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 or 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 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 <invented name>;
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- if you have varicose veins;
- if you have epilepsy (see paragraph "<invented name> and using other medicines");
- 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 [invented name] 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 [invented name] is small.

HOW TO RECOGNISE A BLOOD CLOT

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

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none"> • swelling of one leg or along a vein in the leg or foot especially when accompanied by: <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. 	<p>Deep vein thrombosis</p>

Are you experiencing any of these signs?	What are you possibly suffering from?
<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>	<p>Pulmonary embolism</p>
<p>Symptoms most commonly occurring 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. 	<p>Retinal vein thrombosis (blood clot in the eye)</p>
<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. 	<p>Heart attack</p>
<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>	<p>Stroke</p>
<ul style="list-style-type: none"> • swelling and slight blue discolouration of an extremity; • severe pain in your stomach (acute abdomen) 	<p>Blood clots blocking other blood vessels</p>

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 <invented name> 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 <invented name> 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 <invented name>, 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 [Invented name]	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 <invented name> 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 [invented name] may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop [invented name] 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 <invented name> needs to be stopped.

If any of the above conditions change while you are using <invented name>, 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 <invented name> is very small but can increase:

- with increasing age (beyond about 35 years);
- **if you smoke.** When using a combined hormonal contraceptive like <invented name> 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 (before the age of around 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 <invented name>, 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.

<invented name> 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 occurrence of breast tumours becomes gradually less after stopping the combination hormonal contraceptives. It is important to check your breasts regularly and you should contact your doctor if you feel any lump.

In rare cases, benign liver tumours, in even fewer cases malignant liver tumours have been reported in contraceptive pill users. 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 PapillomaVirus (HPV) increases this risk.

Psychiatric disorders:

Some women using hormonal contraceptives including <Invented name> 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 <invented name>, you may have unexpected bleeding (bleeding outside the tablet-free period). 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 you must do if no bleeding occurs during the 4-day tablet-free interval

If you have taken all the tablets correctly, you 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.

If you are under treatment with <invented name> to postpone periods, bleeding 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.

Only start the next blister, if you are sure that you are not pregnant.

Children and adolescents

<invented name> is only indicated after menarche.

Other medicines and <invented name>

Do not use <Invented name> if you have Hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir as this 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.

<Invented name> can be restarted approximately 2 weeks after completion of this treatment. See section “Do not use < Invented name>”.

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 use <invented name>. They can tell you if you need to take additional contraceptives precautions (for example condoms) and if so, for how long or, whether the use of the other medicine you take must be changed.

Some medicines can have an influence on the blood levels of <invented name> and can make it **less effective in preventing pregnancy**, or can cause unexpected bleeding. These include:

- medicines used for the treatment of:
 - epilepsy (for example, primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine)
 - tuberculosis (for example, rifampicin)
 - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine efavirenz)
 - fungal infections (griseofulvin, ketoconazole)
 - arthritis, arthrosis (etoricoxib)
 - high blood pressure in the blood vessels in the lungs (bosentan)
- the herbal remedy St. John’s wort.

<invented name> **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 medicines.

<invented name> with food and drink

<invented name> 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, breast feeding and fertility

Pregnancy

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

Breast-feeding

Use of <invented name> 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.

Driving and using machines

There is no information suggesting that use of <invented name> affects driving or use of machines.

<invented name> contains lactose.

If you cannot tolerate certain sugars, contact your doctor before you take <invented name>.

3. How to take<INVENTED NAME>

Before you start using <invented name> for the first time you should discuss with your doctor how to use this product during the different phases.

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

Each blister contains 24 tablets.

Take one tablet of <invented name>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.

Tablet intake

Mandatory phase (day 1-24)

Start by taking a pill marked with the correct day of the week. When starting,<invented name> tablets must be taken without interruption for a minimum of 24 days, after which you can either:

- stop taking tablets for a 4-day tablet-free interval during which your period will start,
- or continue to take them for up to 120 days (see flexible phase) by which you delay your period.

Flexible phase (day 25-120)

During the days 25-120, the tablets can be taken without interruption up to a maximum of 120 days. During this period, you may decide yourself if you want to delay your period or take the 4-day tablet-free interval.

If you have decided to continue tablet intake for 120 days, go directly to a 4-day tablet-free interval after completing the 120 days of tablet intake.

With the 4-day tablet-free period you will start your period. This will usually cause bleeding. In the event of continued bleeding (three consecutive days) during tablet taking in the flexible phase (days 25-120), it is advisable to start a 4-day table-free interval which will induce your period. This 4-day tablet-free interval 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 uninterrupted for 24 days.

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

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

It is recommended to start a new blister, which contains 24 tablets, for the mandatory phase and after a 4-day tablet-free interval, in order to help you to follow the instructions on tablet taking correctly.

General dosing rules:

- Any 4-day tablet free interval can only be started if tablet taking has been uninterrupted for 24 days, i.e. after the completion of the mandatory phase.
- After any 4-day tablet free interval, a new mandatory phase starts, i.e. tablets must be taken for a minimum of 24 days before any new break can be scheduled.

Preparation of the blister strip

To help you remember to take the contraceptive, every package of <invented name> comes with 35 (5x7) stickers which have the days of the week printed on them except for initial pack of 24 tablets which contains 7 (1x7) adhesive stickers. You must know the day of the week you are going to start taking the tablets.

Choose the week sticker that starts with the day you begin taking the tablets. For example, if you start on a Wednesday, use the week sticker that starts with "WED".

Stick the week sticker along the top of the blister, where you can read 'place week sticker here'. Now there is a day indicated above every tablet and you can see whether you have taken a certain pill. The arrows show the order you have to take the pills.

If you use <invented name> in this manner, you are protected against pregnancy also during the 4 days when you are not taking tablets.

If you have unfinished blisters, you can take the remaining tablets during the flexible phase. Choose a new week sticker, which has the day of the week you begin taking the remaining tablets, right above the first remaining tablet you are going to take. Stick the new week sticker on top of the previous week sticker. See "*Preparation of the blister strip*".

The prescription of the next blisterpack should be issued in time i.e. prior to the use of the last blister in the pack to ensure that you do not run out of tablets.

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

When can you start with the first blister strip?

- *If you have not used a contraceptive in the previous month*
Begin with <invented name> on the first day of the cycle (that is, the first day of your period). If you start <invented name> on the first day of your menstruation 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 <invented name> 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 (or after the last inactive 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 IUD, on the day of its removal, from an injectable, when the next injection would be due) but in all of these cases you must 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.
- *After having a baby*
You can start <invented name> 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 7 days of <invented name> use.
If, after having a baby, you have had sex before starting <invented name> (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 you want to start <invented name> (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 take more <invented name> than you should

There are no reports of serious harmful results of taking too many <invented name> 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 <invented name> tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

If you forget to take <invented name>

If you forget a tablet (one of the 24 tablets of your blister pack) you must do the following:

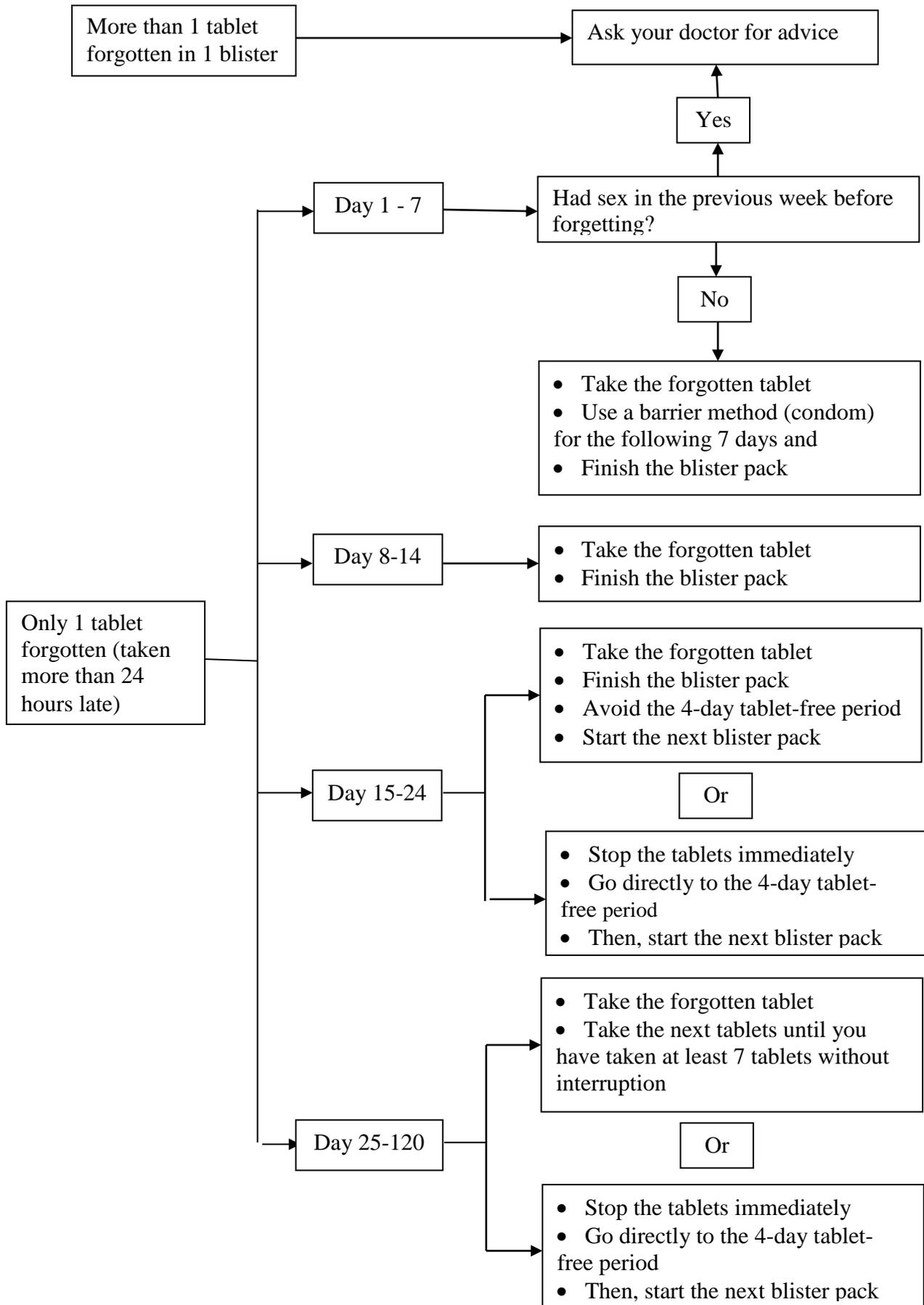
- If you are **less than 24 hours** late taking a tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and then take the following tablets again at the usual time.
- If you are **more than 24 hours** late taking a tablet, the protection against pregnancy may 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 blister pack. Therefore, you should keep the following rules (see also the diagram below):

- **More than one tablet forgotten in this blister strip**
Contact your doctor.
- **One tablet forgotten between days 1 – 7**
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 must realize that there is a risk of pregnancy. In that case, contact your doctor.
- **One tablet forgotten between days 8 – 14**
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 between days 15 – 24**
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 until all the 24 tablets have been taken. Avoid the 4-day tablet-free interval and start the next blister pack (the starting day will be different from the previous).
Most likely, you will have a period at the end of the second blister pack -during the 4-day tablet-free period - but you may have light or menstruation-like bleeding during the second blister pack.
 2. You can also stop the tablets and go directly to the 4-day tablet-free period (**before starting this tablet-free period, record the day on which you forgot your tablet**). If you want to start a new blister pack on the day you always start, reduce the tablet-free period to *less than 4 days*.

If you follow one of these two recommendations, you will remain protected against pregnancy.

- **One tablet forgotten between days 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 that means that you have to take two tablets at the same time, and take the next tablets at the usual time until you have taken at least 7 tablets without interruption.
 2. Stop taking tablets, have a 4-day tablet-free interval (also count the day you missed your tablet) and continue with a new tablet cycle of <invented name>.
- If you have forgotten any of the tablets in a blister, and you do not have a bleeding during your 4-day tablet-free interval, this may mean that you are pregnant. You must contact your doctor before you start the next blister pack



What to do in 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, you must take another tablet from a reserve strip 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, you should follow the advice given under "If you forget to take <invented name>".

If you want to stop taking <invented name>

You can stop taking <invented name> 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 <invented name> 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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, <invented name> 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 <invented name>, 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 <invented name>".

- **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)

- **Common side effects** (between 1 and 10 in every 100 users may be affected):

- mood swings
- headache
- nausea
- breast pain, problems with your periods, such as irregular periods, absence of periods
- emotional lability, depression, libido decreased

- **Uncommon side effects** (between 1 and 10 in every 1,000 users may be affected):

- depression, decreased interest in sex, nervousness, sleepiness
- dizziness, "pins and needles"
- migraine, varicose veins, increase blood pressure
- stomach ache, vomiting, indigestion, intestinal gas, inflammation of the stomach, diarrhoea
- acne, itching, rash
- aches and pains, for instance back pain, limb pain, muscular 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, decreased interest in sex
- lack of energy, increased sweating, fluid retention
- weight increase.

Depression, decreased interest in sex and migraine are common side effects linked to the use of <invented name> in an adaptable regimen of up to 120 days.

- **Rare side effects** (between 1 and 10 in every 10,000 users may be affected):

- 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.
- candida (a 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, for instance inflammation of the eyelids, 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.

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 [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <invented name>

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

Store below 30°C.

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

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. Contents of the pack and other information

What <invented name> contains

- The active substances are ethinylestradiol and drospirenone. Each film-coated tablet contains 0.02 milligram ethinylestradiol and 3 milligram drospirenone.
- The other ingredients are lactose monohydrate, pregelatinized starch (maize), povidone (E1201), croscarmellose sodium, polysorbate 80, magnesium stearate (E470b), poly(vinyl alcohol), titanium dioxide (E171), macrogol, talc (E553b), yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172).

What <invented name> looks like and contents of the pack

- Each blister strip of <invented name> contains 24 film-coated tablets.
- <invented name> is available in a carton containing 1 blister strip or 5 blister strips; total number of tablets per carton is 24 tablets or 120 tablets.
- Each package of <invented name> comes with seven (1x7) or thirty-five (5x7) adhesive stickers which have the days of the week printed on them.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

Laboratorios León Farma, S.A.
C/ La Vallina s/n, Pol. Ind. Navatejera.
24008 - Navatejera, León.
Spain

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

Germany:	Velhari Langzyklus 0.02 mg/3 mg Filmtabletten
Netherlands:	Talia 0.02 mg/3 mg filmomhulde tabletten
Austria:	Velhari Langzyklus 0.02 mg/3 mg Filmtabletten
Belgium:	Perynella 0.02 mg/3 mg filmomhulde tabletten
Spain:	Drosbelalleflex 0.02 mg/3 mg comprimidos recubiertos con película EFG
Finland:	Diza 0,02 mg/3 mg kalvopäällysteiset tabletit
France:	Perynella 3 mg/0,02 mg comprimé pelliculé
Hungary:	Jangee Flexibilis 3mg/0.02 mg
Italy:	Perliq
Luxembourg:	Perynella 0,02 mg/3 mg comprimé pelliculé
Norway:	Diza
Poland:	Naraya Flex
Portugal:	Velhari 0,02 mg/3 mg comprimido revestido
Sweden:	Diza
United Kingdom:	Perliq 0.02 mg/3 mg film coated tablets

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