

Package leaflet: Information for the user**<Invented Name> film-coated tablets**

ethinylestradiol and dienogest

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, 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 hormonal contraceptive tablet for women (combined oral contraceptive, also known as the ‘pill’). It contains a progesterone (dienogest) and an estrogen (ethinylestradiol).

In women in whom a pronounced effect of male hormones (so-called “androgens”) causes acne, clinical tests have proven that <Invented Name> relieves this condition.

<Invented Name> is used to

- prevent pregnancy
- treatment of women with moderately severe acne, with no contraindications for therapy with oral contraceptives and after failure of suitable topical treatments

2. What you need to know before you take <Invented Name>

General notes

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”).

When you should not use <Invented Name>:

You should not use [Invented name] 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, dienogest or another ingredient of this medicine (listed in section 6).
- 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 smoke (see “The ‘pill’ and vascular diseases”).
- If you have or have ever had inflammation in the pancreas if associated with a serious problem processing fats (lipid metabolism disorder).
- If you have or have ever had liver diseases, if the liver values in the blood have not normalized (also in case of Dubin-Johnson and Rotor Syndrome).
- If you have or have ever had liver tumours (benign or malign).
- If you have, have ever had or if you are suspected of having cancer (for example breast cancer or endometrial cancer) affected by sexual hormones.
- If you have any vaginal bleeding of unknown causes.
- If you have no withdrawal bleeding (period), and the cause has not been found.

Warnings and precautions

Talk to your doctor or pharmacist before taking <Invented Name>.

If while you are taking <Invented Name>, one of the diseases or circumstances in section “Do not

take <Invented Name>” occur for the first time, you have to **stop taking <Invented Name> and talk to your doctor immediately.**

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 you have Crohn’s disease or ulcerative colitis (chronic inflammatory bowel disease);
- if you have systemic lupus erythematosus (SLE –; a disease affecting your natural defense 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 [invented name];
- If you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- If you have varicose veins.

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 	Deep vein thrombosis
<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 	Heart attack

<ul style="list-style-type: none"> • 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 	
<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 [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.

[The below wording should be inserted in this section]

- [...]
- 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.
- It is not yet known how the risk of a blood clot with [invented name] compares to the risk with a combined hormonal contraceptive that contains levonorgestrel.
- 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]	Not yet known.

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 30kg/m²);
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50). In this case you could have a hereditary blood clotting disorder;
- if you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of [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 (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 [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.

Stop taking <Invented Name> immediately:

- If you are pregnant or think you might be pregnant.
- If you have signs of phlebitis or blood clots (see “The ‘pill’ and vascular diseases”).
- If your blood pressure constantly increases above 140/90 mmHg (your doctor may advise you to begin taking the ‘pill’ again as soon as your blood pressure has normalized with high blood pressure treatment).
- If surgery is planned (you should stop taking the ‘pill’ at least 4 weeks before surgery) or in case of prolonged immobilization (see also “The ‘pill’ and vascular diseases”).
- If migraine occurs for the first time or gets worse.
- If you have unusually frequent, severe or persistent headache that starts suddenly with signs of the so-called aura (problems in sensations, perception and/or motion).
- If you have severe pains in the upper abdomen (see also “The ‘pill’ and cancer”).
- If your skin and the whites of your eyes become yellow, your urine is brown and your stools are very pale in colour (the so-called jaundice) or if your skin is itching all over your body.
- If you are diabetic (diabetes mellitus) and your blood sugar levels increase suddenly.
- If you suffer from a blood pigment formation (porphyria) and it happens again using <Invented Name>.

Your doctor will monitor you closely:

- If you have heart or kidney disease.
- If you have a tendency to inflammation in the veins (phlebitis) or severe varicose veins.
- If you have circulatory disorders in your hands/feet.
- If your blood pressure level is above 140/90 mmHg.
- If you have a history of problems with the way your body processes fats (lipid metabolism disorders).
- If you have a history of sickle cell anaemia (a hereditary illness affecting red blood cells).
- If you have had liver diseases before.
- If you have a history of gall bladder disease.
- If you have migraine.

- If you have depression.
- If you are diabetic (diabetes mellitus) or if you have a limited capacity to metabolize glucose (reduced glucose tolerance). The dose of medication necessary to treat diabetes may change if you are taking <Invented Name>.
- If you smoke (see “The ‘pill’ and vascular diseases”).
- If you suffer from epilepsy. If there is an increase in epileptic attacks while taking <Invented Name>, you should consider using other contraceptive methods.
- If you suffer from a movement disorder with rapid, jerking movements affecting primarily the face, feet and hands, also known as ‘Saint Vitus’ dance’ (Sydenham’s chorea).
- If you suffer from a chronic inflammatory bowel disease (Crohn’s disease, ulcerative colitis).
- If you have a blood disorder that causes kidney damage (hemolytic uremic syndrome).
- If you suffer from a benign tumour in the muscle layer of the uterus (uterine myoma).
- If you suffer from a certain form of hearing loss (otosclerosis).
- In case of prolonged immobilization (see “The ‘pill’ and vascular diseases”),
- If you are overweight.
- If you suffer from a certain disease of the immune system (systemic lupus erythematosus).
- If you are 40 years old or older.

The ‘pill’ and cancer

Women who take the ‘pill’ were found to have a slightly increased risk of developing breast cancer when compared to women of similar age not taking the ‘pill’. After women stop taking the ‘pill’, this risk is gradually reduced, and after 10 years the difference is no longer detectable between former users of the ‘pill’ and other women of similar age.

Since breast cancer is rare in women under 40 years of age, the number of additional breast cancer cases in women who at the moment are taking the ‘pill’ or who have taken it is quite small in comparison to the overall risk of breast cancer.

Some studies suggest that the long-term use of hormonal contraception is a risk factor for developing cervical cancer in women whose cervix is infected with a certain sexually transmitted virus (human papilloma virus). However, so far it is still unclear to what extent this result is influenced by other factors (such as differences in the number of sexual partners or the use of mechanical contraceptive methods).

Very rarely, benign (non-cancerous) but dangerous **liver tumours** can develop. These tumours can cause life-threatening internal bleedings. **Seek immediate medical treatment if you experience sudden intense abdominal pain.** Studies have shown an increased risk of developing liver cancer in women taking the ‘pill’ for a long time; however, this is extremely rare.

Other diseases

High blood pressure

An increase in the blood pressure of women taking the ‘pill’ has been reported. This occurs more commonly in older users and with a longer use. The frequency of high blood pressure increases with the progesterone content. Use another contraceptive method if you already had diseases caused by high blood pressure or if you suffer from certain kidney diseases (in this case, talk to your doctor; also see “Do not take <Invented Name>”, “Stop taking <Invented Name> immediately” and “Your doctor will monitor you closely”).

Pigmented spots

Occasionally, yellowish-brown pigmented spots (chloasma) may appear on the skin, especially in women who already had them during pregnancy. Women with this disposition therefore should not be exposed to sunlight or ultraviolet light (for example artificial tanning) while they are taking the

- Herbal supplements containing St. John's Wort (*Hypericum perforatum*).

If you are being treated with any of the medicines listed above, a barrier contraception method (condom) should be used in addition to <Invented Name>. With some of the medicines listed above, these additional contraceptive measures should be used at the same time you take the medicine and for 7 to 28 days afterwards, depending on the medicine. Talk to your doctor or pharmacist if you are not sure.

If the barrier method has to be used for a longer period than the tablets contained in the blister pack, then you should start taking the tablets from the next <Invented Name> pack without the 7-day pause. If long-term treatment with one of the medicines listed above is required, talk to your doctor about switching to a non-hormonal method of contraception.

Taking the following medicines at the same time as <Invented Name> may increase your risk of side effects:

- Paracetamol (used against pain and fever),
- Ascorbic acid (vitamin C),
- Atorvastatin (used to reduce blood fat),
- Troleandomycin (an antibiotic),
- Imidazole antimycotics (used against fungal infections) such as fluconazole,
- Indinavir (used to treat HIV infection).

Taking <Invented Name> at the same time as other medicines may affect the way these medicines work:

- Cyclosporine (used to suppress the immune system),
- Theophylline (used to treat asthma),
- Glucocorticoids (for example cortisone),
- Certain benzodiazepines (tranquilizers) such as diazepam, lorazepam,
- Clofibrate (used to reduce blood fats),
- Paracetamol (used against pain and fever),
- Morphine (a very strong pain killer),
- Lamotrigine (used to treat epilepsy).

Please also read the package leaflets of all other medicines you are taking.

Diabetes

In diabetic women, the need for blood sugar-lowering agents (for example insulin) can change.

Laboratory tests

If you need a blood test, tell the doctor or laboratory staff that you are taking an oral contraceptive because this medicine can affect the results of some tests, including the values for the liver, adrenal cortex, kidney and thyroid functions, as well as the amount of certain proteins in the blood, such as proteins affecting lipid (fat) metabolism, carbohydrate metabolism, blood clotting and fibrinolysis. However, these changes generally remain within the normal range.

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 before taking this medicine.

Pregnancy

Do not use <Invented Name> during pregnancy. Before you start taking <Invented Name>, you must be sure that you are not pregnant. If you become pregnant while taking this medicine, you should stop taking <Invented Name> and tell your doctor immediately.

Breast-feeding

Do not take <Invented Name> while breast-feeding, since it may reduce milk production, and low amounts of the active substance may pass into breast milk. You should use non-hormonal contraceptive methods while breast-feeding.

Driving and using machines

<Invented Name> has no effect on the ability to drive and use machines.

<Invented Name> contains lactose

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

3. How to take <Invented Name>

Always take <Invented Name> exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

If the doctor does not say otherwise, the usual dose is 1 tablet of <Invented Name> every day.

How to take <Invented Name>

Swallow the tablet whole, if necessary with some liquid.

The 'pill' must be taken each day, approximately at the same time, following the direction of the arrows until you have finished the pack (that is, 21 consecutive days). The first tablet you should take is the one that corresponds to the day of the week in which you start taking the 'pill', as written on the blister pack (for example "Mo" for Monday).

After you have finished the pack, you need to allow a medicine-free interval for 7 days. During this tablet-free interval, bleeding should begin (so-called withdrawal bleeding). This usually starts on 2 to 4 days after you take last tablet.

Start a new blister pack on the 8th day, whether your bleeding has stopped or not. This means that you should start every blister pack on the same day of the week, and that the withdrawal bleed should occur on the same day every month.

If you use <Invented Name> in this manner, you will be protected against pregnancy during the tablet-free interval.

When to start taking <Invented Name>**If you have not taken any contraceptive 'pills' during the previous month:**

Start taking <Invented Name> on the first day of your cycle: that is on the first day of your menstrual period. If used correctly, contraceptive protection starts on the first day of dosing.

If you start taking <Invented name> between day 2 and 5, use an additional barrier contraception during the first 7 days of taking the 'pill'.

If you switch to <Invented Name> from another 'pill' (with two hormonal active ingredients), a vaginal ring or a patch:

DIENOGEST 2 MG + ETHINYLESTRADIOL 0.03 MG FILM-COATED TABLET

- If you have previously been taking a ‘pill’ (in which a tablet-free interval follows the day when you took the last ‘pill’ containing active ingredient), start taking <Invented Name> on the day after the tablet-free interval.
- If you have previously been taking a ‘pill’ whose package contained tablets without active ingredients (also known as placebo tablets) in addition to tablets containing active ingredients, you then had no tablet-free interval. Start taking <Invented Name> on the day after taking the last tablet without active ingredients. If you do not know exactly which tablet was the last one without active ingredients, ask your doctor or pharmacist.
- If you have previously been using a vaginal ring or a patch, start taking <Invented Name> on the day after the usual ring-free or patch-free interval.

If you switch from a ‘pill’ containing only progesterone (also called ‘mini-pill’):

You can stop taking the ‘mini-pill’ any given day. Start taking <Invented Name> on the next day. During the first 7 days, use an additional non-hormonal contraceptive method (for example condom).

If you switch from an injection product (the so-called ‘three-month injection’), an implant or an ‘IUD’:

Start taking <Invented Name> on the day in which you should have normally been receiving the next injection or on the day in which the implant or the IUD is removed. During the first 7 days, use an additional non-hormonal contraceptive method (for example condom).

After having a baby and if you are not breast-feeding:

Start taking the ‘pill’ no earlier than 21 to 28 days after childbirth. During the first 7 days, use an additional barrier contraceptive method (for example condom). If you have already had sexual relations before starting to take <Invented Name>, you should make sure that you are not pregnant or it is necessary to wait until your next menstrual period before taking this medicine.

While breast-feeding:

If you are breast-feeding and you want to start taking <Invented Name>, talk to your doctor (see “Pregnancy and breast-feeding”).

If you had a miscarriage or terminated pregnancy:

Talk to your doctor about taking <Invented Name>.

Duration of use

You can take <Invented Name> for as long as you want a hormonal contraception method and no health risks are present (see “Do not take <Invented Name>” and “Stop taking <Invented Name> immediately”). Regular medical health exams are strongly recommended (see “Medical consulting / examinations”).

If you take more <Invented Name> than you should:

If you take more tablets than prescribed, talk to your doctor or pharmacist.

Possible signs of overdose include nausea, vomiting (usually after 12 to 24 hours, possibly lasting several days), breast tenderness, dizziness, stomach pain, drowsiness/fatigue; women and adolescents can suffer vaginal bleeding. You must consult a doctor if relatively large amounts have been taken.

If you forget to take <Invented Name>

- If you are **less than 12 hours late** in taking a tablet, the contraceptive effect of <Invented Name> is not reduced. Take the forgotten tablet as quickly as possible and then continue to take the following tablets at the usual times.
- If you are **more than 12 hours late** in taking a tablet, the contraceptive effect can no longer be guaranteed. If no bleeding occurs in the first tablet-free interval after the current blister pack is finished, you may be pregnant. In this case, you have to see your doctor before you start a new blister pack.

In general, you should consider two points:

- the intake of the tablet must not be interrupted for more than 7 days
- for adequate contraceptive protection after missing a tablet, the tablets must be taken without interruption for 7 days

Follow the instructions below if you have forgotten to take a tablet:

If you forgot 1 tablet in week 1:

Take the forgotten tablet as soon as possible, even if this means taking two tablets at the same time. Then continue taking the tablets as usual. In the next 7 days, however, use an additional barrier contraceptive method (for example condom). If you have had sexual relations the week before you forgot to take the tablets, there is a possibility that you are pregnant. The probability of pregnancy becomes higher the closer the forgotten tablet is to the tablet-free interval. The nearer both of these are to the usual tablet-free interval, the greater is the likelihood of pregnancy.

If you forgot 1 tablet in week 2

Take the forgotten tablet as soon as possible, even if this means taking two tablets at the same time. The following tablets can be taken at the usual times. If you took <Invented Name> correctly in the 7 days before the forgotten tablet, the contraceptive effect of the 'pill' is not affected and you do not have to use any additional contraceptive method. If this is not the case or if you forgot to take more than 1 tablet, use an additional barrier method of contraception (for example condom) for the next 7 days.

If you forgot 1 tablet in week 3:

The contraceptive protection is not fully guaranteed. By adjusting the 7-day tablet-free interval, you can still maintain the contraceptive effect. If you follow one of the two procedures explained below, there is no need for additional contraceptive measures, but this is only if you have been taking <Invented Name> correctly during the 7 days before you forgot to take a tablet. If this was not the case, proceed as described below in point 1. Additionally, in the next 7 days, use an additional barrier contraceptive method (for example condom).

Option 1: Take the forgotten tablet as soon as possible, even if this means taking two tablets at the same time. The following tablets can be taken at the usual times. Skip the tablet-free interval, start taking the tablets from the next blister pack. It is highly likely that you will have no withdrawal bleeding until you have finished this second blister pack; however, you may experience breakthrough bleeding and spotting.

or

Option 2: You can stop taking tablets from the current blister pack immediately, and start the tablet-free interval of no more than 7 days (**including the day you forgot the tablet**); then continue with tablets from the next blister pack. If you would like to start using the new blister pack on your usual week day, make the tablet-free interval shorter than 7 days.

If you have forgotten more than 1 tablet in the current blister pack:

If you forgot to take more than 1 tablet from the current blister pack, you are no longer protected against pregnancy.

The probability of pregnancy increases the more tablets you have forgotten and the closer they are to the tablet-free interval. Until your next usual withdrawal bleeding, use an additional barrier contraceptive method (for example condom). If no bleeding occurs after you finish the current blister pack, in the first normal pause, you may be pregnant. In this case consult your doctor before starting a new blister pack.

If you vomit or have diarrhoea

If you have digestive disturbances, such as vomiting, or diarrhoea within 4 hours after taking a tablet, the active ingredient may not be fully absorbed in your body. In these cases, follow the instructions that apply if you forgot to take a tablet and noticed it within 12 hours. If you do not want to deviate from your normal rhythm, take a replacement tablet from another blister pack. If the gastro-intestinal symptoms persist for several days or are recurrent, use a barrier contraception method (for example condom) and inform your doctor.

If you want to delay the withdrawal bleeding (your period)

If you want to change the time of the withdrawal bleeding, you should continue taking the tablets from the next blister pack of <Invented Name> directly, without any tablet-free interval. The withdrawal bleeding can be postponed as much as you want, but only until the second blister pack is over. During this time, you may experience breakthrough bleeding or spotting. After the following regular 7-day tablet-free interval, you can continue taking <Invented Name> as usual.

If you stop taking <Invented Name>

You can stop taking <Invented Name> at any time. If you do not want to become pregnant, ask your doctor about other reliable contraceptive methods.

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

4. Possible side effects

Like all medicines, this medicine can have 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]”.

The serious side effects associated with the ‘pill’ are listed in section 2, “What you need to know before you take <Invented Name>”. There you can find detailed information. Talk to your doctor immediately if necessary.

The following side effects are possible when taking <Invented Name>:

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

- Headaches
- Chest pain, including chest discomfort and breast tenderness

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

- Inflammation of the genitals (vaginitis / vulvovaginitis), vaginal yeast infections (candidiasis, vulvovaginal infections)
- Increase in appetite
- Depressed mood
- Vertigo
- Migraine
- High or low blood pressure, in rare cases increased diastolic blood pressure (lower blood pressure value),
- Abdominal pain (including pain in the upper and lower abdomen, discomfort / bloating),
- Nausea, vomiting or diarrhoea,
- Acne
- Hair loss (alopecia),
- Skin rash (including spot-like rash),
- Itching (sometimes over the entire body)
- Irregular menstrual bleeding including heavy bleeding (menorrhagia), minor bleeding (hypomenorrhoea), irregular bleeding (oligomenorrhoea) and absence of bleeding (amenorrhoea),
- Spotting (vaginal hemorrhage and metrorrhagia)
- Painful menstruation (dysmenorrhoea), pelvic pain,
- Breast enlargement including breast swelling, breast oedema,
- Vaginal discharge,
- Ovarian cysts,
- Fatigue including weakness, fatigue and general malaise,
- Weight change (increase, decrease or fluctuation)

Rare (may affect up to 1 in 1000 people):

- Inflammation in the fallopian tubes or ovaries
- Inflammation of the cervix (cervicitis)
- Urinary tract infection, bladder infection (cystitis)
- Breast infection (mastitis)
- Fungal infections (such as Candida), viral infections, cold sores
- Flu (influenza), bronchitis, upper respiratory infections, sinus infection (sinusitis)
- Asthma
- Increase in respiratory rate (hyperventilation)
- Benign growths in the uterus (fibroids)
- Benign growths in the fatty tissue of the breast (breast lipomas)
- Anaemia
- Allergic reactions (hypersensitivity)
- Masculinization (virilism)
- Loss of appetite (anorexia)
- Depression, mood swings, irritability, aggression
- Insomnia, sleep disorders
- Vascular disorders of the brain or the heart, stroke
- Dystonia (muscle disorder that can cause an abnormal posture or abnormal movement)
- Dry or irritated eyes
- Visual disorders
- Sudden loss of hearing, hearing impairment
- Tinnitus
- Balance disorders

- Fast heart rhythm
- Thrombosis, pulmonary embolism
- Inflammation of the veins (phlebitis, thrombophlebitis)
- Varicose veins (varicosis) veins aches or pains
- Dizziness or fainting when standing up from sitting or lying down (orthostatic hypotension)
- Flushing
- Inflammation of the stomach lining (gastritis), inflammation of the intestine (enteritis)
- Indigestion (dyspepsia)
- Skin reactions / skin complaints including allergic skin reaction, neurodermatitis / atopic dermatitis, eczema, skin redness and irritation (psoriasis)
- Excessive sweating
- Golden-brown pigmented spots (called pregnancy spots) especially on the face (chloasma), pigment disorders / increased pigmentation
- Oily skin (seborrhea)
- Dandruff
- Masculine hair growth (hirsutism)
- Orange skin (cellulite)
- Skin nevus (blood vessels that look like a spider web, with a central red spot on the skin)
- Back pain, chest pain
- Ailments of the bones and muscles, muscle pain (myalgia), pain in arms and legs
- Cervical dysplasia (abnormal growth of cells on the surface of the cervix)
- Pain or cysts on the uterine appendages (fallopian tubes and ovaries)
- Breast cysts, benign growths in the breast (fibrocystic breast disease), swelling of tissue outside of the breasts (breasts accessory)
- Pain during intercourse
- Breast gland secretion, breast discharge
- Menstrual disorders
- Peripheral oedema (fluid retention)
- Flu-like illness, inflammation, pyrexia (fever)
- Increase in triglyceride and cholesterol levels in the blood (hypertriglyceridemia, hypercholesterolemia)

Not known (frequency cannot be estimated from the available data)

- Increased or decreased sex drive (libido)
- Contact lens intolerance,
- Hives (urticaria),
- Painful, red bumps under the skin (erythema nodosum or multiforme).

If you suffer from hereditary angioedema, medicines containing estrogen can cause or worsen symptoms of angioedema (see section "Warnings and precautions").

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.

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

Do not store above 30°C

Keep the blister in the outer carton in order to protect from the light.

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 dienogest and ethinylestradiol. One coated tablet contains 2.0 mg of dienogest and 0.03 mg of ethinylestradiol.

- The other ingredients are:

Tablet core: lactose monohydrate, magnesium stearate, maize starch, povidone.

Film-coating: aquarius coating system containing: hypromellose 2910, macrogol 400 (PEG), titanium dioxide.

What <Invented Name> looks like and contents of the pack

<Invented Name> is a white, round, biconvex film-coated tablet.

<Invented Name> is available in packages containing 21, 3x21 and 6x21 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer**Marketing Authorisation Holder**

<[To be completed nationally]>

Manufacturer:

Laboratorios León Farma SA

La Vallina s/n, Pol. Ind. Navatejera,

Navatejera-24008 León Spain

This leaflet was last revised in MM/YYYY