PACKAGE LEAFLET

Package leaflet: Information for the user

Aulfin 2 mg/0.02 mg prolonged-release tablets

dienogest / ethinylestradiol

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.

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”).

What is in this leaflet

1. What <TRADENAME> is and what it is used for

<TRADENAME> is a combined oral contraceptive pill and is used:
- To prevent pregnancy
- Treatment of hirsutism in women with Polycystic Ovary Syndrome (PCOS).

Each of the 24 pale white tablets contains a small amount of two different female hormones, namely dienogest and ethinylestradiol. The 4 green tablets contain no active substances and are called placebo tablets.
Contraceptive pills that contain two hormones are called “combination pills”.

2. What you need to know before you take <TRADENAME>

General notes

Before you start using <TRADENAME> 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 <TRADENAME>, 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 <TRADENAME>, or where the reliability of <TRADENAME> may be decreased. In such situations you should either not have intercourse or you should take extra non-hormonal contraceptive precautions, e.g. use a condom or another barrier method. Do not use calendar or temperature methods. These methods can be unreliable because <TRADENAME> alters the monthly changes of body temperature and cervical mucus.

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

If you take the pill, your doctor will request you are tested regularly. Normally, you should consult your doctor at least once a year.

Do not use <TRADENAME>

You should not use <TRADENAME> 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 <TRADENAME> if you:
- are allergic to ethinylestradiol or dienogest or any of the other ingredients of this medicine (listed in section 6);
- have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolism, PE) or other organs;
- 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;
- need an operation or if you are off your feet for a long time (see section 2 “Blood clots”);
- have ever had a heart attack or a stroke;
- 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);
- 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
- have (or have ever had) a type of migraine called “migraine with aura”;
- have (or have ever had) severe liver disease, unless blood liver function tests have returned to normal;
- have (or have ever had) benign or malignant liver tumours;
- have (or have ever had) or if you are suspected of having cancers (e.g. of the breast or womb lining) that are affected by sex hormones;
- have any unexplained bleeding from the vagina;
- have hepatitis C and are taking medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see section 2 “Other medicines and <TRADENAME>”).

If any of the above situations occur while taking <TRADENAME>, you must stop taking the product immediately and consult your doctor. In the meantime, you should use a different, non-hormonal method of contraception. For further information, see also section “Warnings and precautions”.

Warnings and precautions
Talk to your doctor or pharmacist before taking <TRADENAME>.

When you need to take special care with <TRADENAME>

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" [thrombosis] section below).

For a description of the symptoms of these serious side effects please go to section 2 "How to recognise a blood clot".

Tell your doctor if any of the following conditions apply to you.
In some situations, special care is needed when taking <TRADENAME> or any other combination pill, and it may be necessary that you are regularly checked by your doctor.

If the condition develops, or gets worse while you are using <TRADENAME>, you should also tell your doctor if you:
- have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- have systemic lupus erythematosus (SLE – a disease affecting your natural defence system);
- have haemolytic uraemic syndrome (HUS – a disorder of blood clotting causing failure of the kidneys);
- have sickle cell anaemia (an inherited disease of the red blood cells);
- 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);
- need an operation, or you are off your feet for a long time (see section 2 "Blood clots").
- 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 <TRADENAME>;
- have an inflammation in the veins under the skin (superficial thrombophlebitis);
- have varicose veins;
- have heart valve defects or heart rhythm disorders;
- have breast cancer in close relatives;
- have liver or gallbladder disease or gallstones;
- have jaundice or itching due to bile congestion;
- have patchy, yellow-brownish discoloration of the skin, especially on the face (chloasma), or if you have experienced this during an earlier pregnancy; in this case, strong sunlight and UV radiation must be avoided;
- have certain problems in haemoglobin formation (porphyria);
- suffer from depression;
- suffer from epilepsy;
- have St. Vitus' dance (Sydenham Chorea);
- had blistery rash during an earlier pregnancy (herpes gestationis);
- have inner ear hearing loss (otosclerosis-related hearing loss);
- experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Products containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema.

Do not hesitate to ask your doctor or pharmacist for advice if you have any doubts about the use of <TRADENAME>.

BLOOD CLOTS
Using a combined hormonal contraceptive such as <TRADENAME> 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 the 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 <TRADENAME> 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

- 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 <TRADENAME> 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 <TRADENAME> 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 dienogest and ethinylestradiol such as <TRADENAME> between about 8 and 11 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 dienogest and ethinylestradiol 2 mg/0.03 mg and different posology with a higher dose of ethinylestradiol than <TRADENAME>	About 8–11 out of 10,000 women

Factors that increase your risk of a blood clot in a vein
The risk of a blood clot with <TRADENAME> 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/m^2);
- 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 <TRADENAME> may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop <TRADENAME> 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 <TRADENAME> needs to be stopped.

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

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

Other factors affecting blood clots
If you have polycystic ovary syndrome (PCOS), it can sometimes increase the chances of developing certain health issues that may affect the heart and blood vessels. These include things like weight gain, your cells not responding well to insulin, high levels of fat in the blood and a slightly higher risk of blood clots.
Your doctor should evaluate these risks before starting treatment with a combined oral contraceptive.
If you don't see any improvement after taking <TRADENAME> for 6 – 12 months, you should talk to your doctor about trying a different treatment. This is to avoid staying on the same medicine for too long, which could increase the risk of blood clots.

<TRADENAME> and cancer
Breast cancer has been detected slightly more often in women using combination pills, but it is not known whether this is caused by the pill. It is possible that these women were simply examined more thoroughly and more frequently, meaning that the breast cancer was detected earlier. The risk of breast cancer gradually decreases after stopping the combined hormonal contraceptive. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

In women using combination pills for a relatively long time, studies have reported cases of cervical cancer. It is currently unknown whether it is caused by the pill or connected with sexual behaviour (e.g. more frequent changes of partner) and other factors.

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

Psychiatric disorders
Some women using hormonal contraceptives including <TRADENAME> 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 <TRADENAME>, you may have unexpected bleeding (bleeding outside the placebo days). If this bleeding lasts longer than a few months, or if it reappears after some months, your doctor must investigate the cause.

What you must do if no bleeding occurs in the placebo days
If you have taken all the white active tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant.
If the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Do not start the next blister pack until you are sure that you are not pregnant.

Other medicines and <TRADENAME>

Always tell your doctor which medicines or herbal products you are already using including any medicines obtained without a prescription. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you use <TRADENAME>. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long.

Some medicines
- can have an influence on the blood levels of <TRADENAME>
- can make it **less effective in preventing pregnancy**
- can cause unexpected bleeding.

These include:
- medicines used for the treatment of:
  - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efavirenz)
  - epilepsy (e.g. phenobarbital, phenytoin, primidone, carbamazepine, oxcarbazepine, topiramate or felbamate)
  - tuberculosis (e.g. rifampicin)
  - fungal infections (griseofulvin, azole antifungals, e.g. itraconazole, voriconazole, fluconazole)
  - bacterial infections (macrolide antibiotics, e.g. clarithromycin, erythromycin)
  - certain heart diseases, high blood pressure (calcium channel blockers, e.g. verapamil, diltiazem)
  - arthritis, arthrosis (etoricoxib)
- the herbal remedy St. John's wort, which is used to treat certain types of depression

<TRADENAME> may **influence the effect** of other medicines, e.g.
- lamotrigine
- cyclosporine
- theophylline
- tizanidine

Do not use <TRADENAME> if you have Hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir and sofosbuvir/velpatasvir/voxilabprevir as these products may cause increases in liver function blood test results (increase in ALT liver enzyme). Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicinal products. <TRADENAME> can be restarted approximately 2 weeks after completion of this treatment. See section "Do not use <TRADENAME>".

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

Interactions with laboratory tests
The use of <TRADENAME> can affect the results of certain laboratory tests, including values of liver, adrenal cortex, kidney and thyroid function, as well as the amount of certain proteins in the blood, e.g. proteins that affect fat digestion, carbohydrate metabolism or blood clotting and fibrinolysis. However, these changes generally remain within the normal range.

Pregnancy and breast-feeding

Pregnancy
<TRADENAME> must not be taken during pregnancy. You must not be pregnant before you start taking <TRADENAME>. If you become pregnant while taking <TRADENAME>, stop taking it immediately and contact your doctor.

Breast-feeding
It is not recommended to take <TRADENAME> if you are breast-feeding.
If you want to breast-feed, your doctor will recommend you a suitable form of contraception.

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

Driving and using machines
No effects on the ability to drive and operate machines were observed.

<TRADENAME> contains lactose
Each white active tablet of <TRADENAME> contains 19 mg lactose (as lactose monohydrate). Each green placebo tablet contains 56 mg lactose (as lactose monohydrate).
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take <TRADENAME>

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Each blister pack contains 28 tablets. Take one pill of <TRADENAME> at the same time every day, on 28 consecutive days following the direction indicated by the arrows without fail as follows: take one white active tablet on each of the first 24 days and then one green placebo tablet on each day of the last 4 days.

After taking the last tablet, continue taking <TRADENAME> the following day starting another blister pack with no free interval between the blisters. You will always start a new blister pack on the same day of the week. As there are no breaks in taking the medication it is important that you already have the next blister pack ready before finishing one.

To help you keep track, there are 7 stickers each with the 7 days of the week for each strip of <TRADENAME>. 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 on the <TRADENAME> strip, where it reads “Place day label here”. There is now a day indicated above every tablet and you can see whether you have taken a certain pill. The arrows show the order you are to take the pills.

During the 4 days when you are taking the green placebo tablets (the placebo days), bleeding should begin (so-called withdrawal bleeding). This usually starts on the 2nd or 3rd day after the last white active tablet of <TRADENAME>. Once you have taken the last green tablet, you should start with the following strip, whether your bleeding has stopped or not. This means that you should start every strip on the same day of the week, and that the withdrawal bleed should occur on the same days each month.

If you use <TRADENAME> in this manner, you are protected against pregnancy also during the 4 days when you are taking a placebo tablet.

Please note the instructions in section 3 “If you forget to take <TRADENAME>” to maintain the contraceptive effect.

Method and route of administration

Swallow each pill, if necessary with a small amount of water. It does not matter whether you take the tablets fasting or with meals.

When you can start taking <TRADENAME> for hormonal contraception

If have not used a contraceptive with hormones in the previous month

Begin with <TRADENAME> on the first day of the cycle (that is, the first day of your period). If you start <TRADENAME> 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.

If you are changing from a combined hormonal contraceptive or combined contraceptive vaginal ring or patch
You can start <TRADENAME> preferably on the day after the last active tablet (the last tablet containing the active substances) of your previous pill, but at the latest on the day after the tablet-free days of your previous pill finish (or after the last inactive tablet of your previous pill). If you are switching from a vaginal ring or patch to <TRADENAME> you should preferably start taking on the day of removal of the last ring or patch of a cycle pack, but by no later than when the next application would be due.

If you were using 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.

If you are starting <TRADENAME> after a termination of pregnancy that occurred during the first trimester
You can normally start immediately but should follow the advice of your doctor before doing so.

If you are starting <TRADENAME> after giving birth or after a termination of pregnancy that occurred during the second trimester
You can start <TRADENAME> between 21 and 28 days after giving birth or after termination of pregnancy. If you start later, you are advised to use an additional barrier contraceptive method during the first 7 days of taking the pill. If you have had sex before starting <TRADENAME> be sure you are not pregnant or wait until your next period.

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

When you can start taking <TRADENAME> for the treatment of hirsutism in women with Polycystic Ovary Syndrome

You can start at any time, regardless of your menstrual cycle. If you seek also hormonal contraception, see section “When you can start taking <TRADENAME> for hormonal contraception”.

<u>Duration of use</u>
Your doctor will tell you for how long you should use this pill.

If you take more <TRADENAME> than you should

There are no reports of serious harmful effects after taking too many <TRADENAME> tablets. If you take several tablets at once, symptoms that may occur are nausea, vomiting and slight vaginal bleeding.

If you forget to take <TRADENAME> for hormonal contraception

If you miss a **white, active tablet** (tablets 1-24 of your blister-strip), you must do the following:

- **If you realise you have missed a white tablet within 24 hours of the time you normally take your 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 realise you have missed a white tablet more than 24 hours after you normally take it**, 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 white tablet at the beginning or at the end of the strip. Therefore, you should keep to the following rules:

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

  - **One tablet forgotten between days 1 - 7 (first row)**
    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 realise that there is a risk of pregnancy. In that case, contact your doctor.

  - **One tablet forgotten between days 8 - 14 (second row)**
    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. If you have taken the tablets correctly in the 7 days preceding the first missed tablet the protection against pregnancy is not reduced, and you do not need to take extra precautions.

  - **One tablet forgotten between days 15 - 24 (third or fourth row)**
    You can choose between the following options without having to use additional contraceptives, provided you have been taking the pill correctly on the 7 days before forgetting the tablet. If this is not the case, you should follow the first of these two options and use additional protective measures for 7 days.
    1. Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. Instead of taking the green placebo tablets on this strip, throw them away, and start the next strip (the starting day will be different). Most likely, you will have a period at the end of the second strip - while taking the green placebo tablets - but you may have light or menstruation-like bleeding during the second strip.
    2. You can also stop the active white tablets and go directly to the 4 green placebo tablets (before taking the placebo tablets, record the day on which you forgot your tablet). If you want to start a new strip on the day you always start, take the placebo tablets for less than 4 days.

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

  - If you have forgotten any of the tablets in a strip, and you do not have a bleeding during the placebo days, this may mean that you are pregnant. You must contact your doctor before you start the next strip.

If you have forgotten one or more green tablets, you are still protected provided that the time between the last white tablet of the current blister pack and the first white tablet of the next blister pack is not greater than 4 days.

If you forget to take <TRADENAME> for the treatment of hirsutism

The efficacy in the treatment of hirsutism may be reduced in case of missed doses. If you have forgotten one or more tablets, you should take one tablet only, as soon as you remember, and then continue the next day at your usual time.

There are no consequences if you have forgotten one or more green tablets, provided that the time between the last white tablet of the current blister pack and the first white tablet of the next blister pack is not greater than 4 days.

What to do in the case of vomiting or severe diarrhoea

If you vomit or have severe diarrhoea, there is a risk that the active substance in the pill will not be fully absorbed by your body, the situation is almost the same as forgetting a tablet. In these cases, if <TRADENAME> is being used for hormonal contraception, an additional method of contraception should be taken, ask your doctor for advice.

If you vomit or have severe diarrhoea within 3-4 hours after taking your white active tablet of <TRADENAME>, you must take another white tablet from another blister pack as soon as possible for all the indications. If possible, take it within 24 hours of when you normally take your pill. Additional contraceptive precautions are not necessary. If this is not possible or 24 hours have passed, you should follow the advice given in the section "If you forget to take <TRADENAME>" above, for each indication.

Delaying your period: What you need to know

Even if it is not recommended, you can delay your period by not taking the green placebo tablets from the 4th row and going straight to a new strip of <TRADENAME> and finishing it. You may experience light or menstruation-like bleeding while using this second strip. Finish this second strip by taking the 4 green tablets from the 4th row. Then start your next strip.
You might ask your doctor for advice before deciding to delay your menstrual period.

Changing the day of the week when your monthly period starts: What you need to know

If you take the tablets according to the instructions, then your period will begin during the placebo days. If you have to change this day, reduce the number of placebo days – when you take the green placebo tablets – (but never increase them, 4 is the maximum!). For example, if you start taking the placebo tablets on a Friday, and you want to change this to a Tuesday (3 days earlier) you must start a new strip 3 days earlier than usual. You may not have any bleeding during this time. You may then experience light or menstruation-like bleeding.
If you are not sure what to do, consult your doctor.

If you stop taking <TRADENAME>

You can stop taking <TRADENAME> whenever you want. From the day you stop you are no longer protected against pregnancy.

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

4. Possible side effects

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

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 <TRADENAME>".

Serious side effects

The serious reactions associated with the use of the pill as well as the associated symptoms are described in the sections: “What you need to know before you take < TRADENAME>”, “Blood clots”, “<TRADENAME> and cancer”.
Please read these sections of the package leaflet for detailed information and contact your doctor if necessary.

Contact a doctor immediately if you experience any of the following symptoms of angioedema: swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also section 2. “Warnings and precautions”).

Other possible side effects

The following side effects, listed by frequency, were observed in clinical studies with <TRADENAME>:

Common side effects (may affect up to 1 in 10 people):
- vaginal infections including fungal infection of the vulva and vagina and bacterial vaginosis
- changes in sexual desire, altered mood (including depressed mood)
- headache
- nausea, abdominal pain
- acne
- breast discomfort or pain, painful periods, abnormal bleeding between regular menstrual periods
- weight gain and increased levels of thyroid stimulating hormone in blood

Uncommon side effects (may affect up to 1 in 100 people):
- urinary tract infection, presence of bacteria in the urine (bacteriuria)
- hypothyroidism (underactive thyroid)
- appetite changes, including decreased or increased appetite, high level of glucose in blood.
- fluid retention
- insulin resistance
- depression, anxiety, mental disorders (including mental impairment, borderline personality disorder, and panic attack), sleep disorder (like insomnia or somnolence)
- dizziness, migraine
- elevated blood pressure (hypertension)
- harmful blood clots in a leg or foot vein (deep vein thrombosis) or the lung (pulmonary embolism)
- hot flushes
- abdominal distension
- vomiting, diarrhoea, flatulence
- hair loss (alopecia)
- itchy skin (pruritus), skin irritation (dermatitis), rash
- increased sweating (hyperhidrosis)
- skin disorders, dry skin
- pain in the arms and legs
- absence of menstrual periods, abnormal vaginal bleeding, altered menstrual bleeding, pelvic pain, ovarian cysts, vaginal discharge and vulvovaginal discomfort, including itching or dryness, vulvovaginal inflammation, cervical dysplasia (abnormal cell growth on the surface of the cervix), pain/spasms during sexual intercourse (dyspareunia)
- fatigue (tiredness)
- swelling
- altered blood test results: elevated levels of triglycerides, creatine phosphokinase, cholesterol, hepatic enzymes, lactate dehydrogenase and prolactin in the blood,

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

- inflammation of the tympanic membrane, that can cause hearing impairment and earache (myringitis)
- genital herpes
- benign tumor of breast (fibroadenoma of breast)
- lower number of leukocytes (white blood cells) in the blood
- hyperthyroidism (overactive thyroid)
- imbalance of lipids in blood (dyslipidemia)
- perception of taste altered (dysgeusia)
- partial loss of tactile sensation (hypoaesthesia)
- burning or prickling sensation that is usually felt in the hands, arms, legs, or feet, but can also occur in other parts of the body (paraesthesia)
- eye itching, visual impairment
- vertigo
- rapid heart rhythm (palpitations)
- blood pressure fluctuation
- haematoma (a collection of blood out of the vessels under the skin)
- venous disorders including spider veins or varicose veins
- nosebleed (epistaxis)
- indigestion (dyspepsia)
- constipation
- gastrooesophageal reflux
- tooth sensitivity (hyperaesthesia teeth)
- urticaria, chloasma (golden brown pigment spots)
- joint pain (arthralgia)altered urine test results: presence of red blood cells and white blood cells in urine.
- irregular thickening of the uterine lining
- genital discomfort
- general feeling of unwell, lack of energy
- altered blood test results: increased levels of fibrin D dimer
- abnormal blood pressure

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 <TRADENAME>

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 carton and the blister strip after “EXP”. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

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

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What <TRADENAME> contains

White tablet:
- The active substances are dienogest and ethinylestradiol.
- The other excipients are:
  Tablet core: Lactose monohydrate, hypromellose (E 464), povidone, magnesium stearate (E 470b), silica colloidal anhydrous.
  Tablet coating: Polyvinyl alcohol-partially hydrolyzed, titanium dioxide (E 171), macrogol (E 1521), talc (E 553b).

Green tablet:
- There is no active substance.
- The other excipients are:
  Tablet core: Lactose monohydrate, maize starch, povidone, silica colloidal, magnesium stearate (E 470b).
  Tablet coating: Hypromellose (E 464), triacetin (E 1518), polysorbate 80, titanium dioxide (E 171), indigo carmine aluminium lake, iron oxide yellow.

What <TRADENAME> looks like and contents of the pack

<TRADENAME> comes in the form of prolonged-release tablets.

Each box contains 1, 3, 6 or 13 blister packs, each containing 28 tablets (24 white active tablets and 4 green inactive tablets).

A carton case for the blister is enclosed.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
[To be completed nationally]

This leaflet was last revised in 2026-03-04.

Detailed information on this medicine is available on the website of {name of Member State Agency (link)}.