Package leaflet: Information for the user

Carmenelle 0.02 mg/3 mg film-coated tablets

Ethinylestradiol/Drospirenone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do no 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4

Important things to know about combined hormonal contraceptives (CHCs):

- They are one of the most reliable reversible methods of contraception if used correctly
- They slightly increase the risk of having a blood clot in the veins and arteries, especially in the first year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks
- Please be alert and see your doctor if you think you may have symptoms of a blood clot (see section 2 "Blood clots")

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1. What Carmenelle is and what it is used for

Carmenelle is a contraceptive pill and is used to prevent pregnancy.

Each tablet contains a small amount of two different female hormones, namely drospirenonen and ethinylestradiol.

Contraceptive pills that contain two hormones are called "combination" pills.

2. What you need to know before you take Carmenelle

General notes

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

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

When you should not use Carmenelle

You should not use Carmenelle 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 have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs
- if you know you have a disorder affecting your blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies;
- if you need an operation or if you are off your feet for a long time (see section 'Blood clots');
- if you have ever had a heart attack or stroke

- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA – temporary stroke symptoms);
- if you have any of the following diseases that may increase your risk of a clot in the arteries:
    - severe diabetes with blood vessel damage
    - very high blood pressure
    - a very high level of fat in the blood (cholesterol or triglycerides)
    - a condition known as hyperhomocysteinaemia
- if you have (or have ever had) a type of migraine called 'migraine with aura';
- if you have (or have ever had) an inflammation of the pancreas (pancreatitis)
- if you have (or have ever had) a liver disease and your liver function is still not normal
- if your kidneys are not working well (renal failure)
- if you have (or have ever had) a tumour in the liver
- if you have (or have ever had) or if you are suspected of having breast cancer or cancer of the genital organs
- if you have any unexplained bleeding from the vagina
- if you are allergic to ethinylestradiol or drospirenone, or any of the other ingredients of this medicine (listed in section 6). This may cause itching, rash or swelling.

When to take special care with Carmenelle

When should you contact your doctor?

<u>Seek urgent medical attention</u>

- 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.

In some situations you need to take special care while using Carmenelle or any other combination pill, and your doctor may need to examine you regularly.
If the condition develops, or gets worse while you are using Carmenelle, 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 defence system);
- if you have haemolytic uraemic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys);
- if you have sickle cell anaemia (an inherited disease of the red blood cells);
- if you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas);
- if you need an operation, or you are off your feet for a long time (see in section 2 'Blood clots');
- if you have just given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking Carmenelle;
- If you have an inflammation in the veins under the skin (superficial thrombophlebitis);

- If you have varicose veins.
- 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 epilepsy (see page 9 "Carmenelle 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 chloasma (a discoloration of the skin especially of the face or neck known as "pregnancy patches"). If so, avoid direct sunlight or ultraviolet light.
- if you have hereditary angioedema, products containing oestrogens may cause or worsen symptoms. You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing.

BLOOD CLOTS

Using a combined hormonal contraceptive such as Carmenelle 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 Carmenelle **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

Are you experiencing any of these signs?	What are you possibly suffering from?
• 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; • rapid or irregular heartbeats	Heart attack
• 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 Carmenelle 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 Carmenelle 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 Carmenelle, 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 Carmenelle	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 Carmenelle 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/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 Carmenelle may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Carmenelle 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 Carmenelle needs to be stopped.
If any of the above conditions change while you are using Carmenelle, 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 Carmenelle is very small but can increase:

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

Carmenelle 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 regularly check your breasts and you should contact your doctor if you feel any lump.

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

Bleeding between periods

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

What to do if no bleeding occurs during the gap week

If you have taken all the tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant.
If the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Do not start the next strip until you are sure that you are not pregnant.

Other medicines and Carmenelle

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 Carmenelle. 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 Carmenelle and can make it **less effective in preventing pregnancy,** or can cause unexpected bleeding. These include:

- medicines used for the treatment of
    - epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine)
    - tuberculosis (e.g.; rifampicin)
    - HIV and hepatitis C Virus so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efavirenz or other infections (griseofulvin)
    - high blood pressure in the blood vessels in the lungs (bosentan)
- the herbal remedy St John's wort

Carmenelle 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)

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

Taking Carmenelle with food and drink and alcohol

Carmenelle 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 hormone contraceptives can affect the results of some tests.

Pregnancy, breast-feeding and fertility

Pregnancy

If you are pregnant, do not take Carmenelle. If you become pregnant while taking Carmenelle stop immediately and contact your doctor. If you want to become pregnant, you can stop taking Carmenelle at any time (see also "If you want to stop taking Carmenelle").

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

Breast-feeding

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

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

Driving and using machines

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

Carmenelle 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 Carmenelle

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

Take one tablet of Carmenelle 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.

The strip contains 21 tablets. Next to each tablet is printed the day of the week that it should be taken. If, for example, you start on a Wednesday, take a tablet with "WED" next to it. Follow the direction of the arrow on the strip until all 21 tablets have been taken.

Then take no tablets for 7 days. In the course of these 7 tablet-free days (otherwise called a stop or gap week) bleeding should begin. This so-called "withdrawal bleeding" usually starts on the 2nd or 3rd day of the gap week.

On the 8th day after the last Carmenelle tablet (that is, after the 7-day gap week), 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 Carmenelle in this manner, you are also protected against pregnancy also during the 7 days when you are not taking a tablet.

When can you start with the first strip?

- *If you have not used a contraceptive with hormones in the previous month.*
  Begin with Carmenelle on the first day of the cycle (that is the first day of your period). If you start Carmenelle on the first day of your period you are immediately protected against pregnancy. You may also begin on day 2-5 of the cycle, but then you must use extra protective measures (for example, a condom) for the first 7 days.

- *Changing from a combination hormonal contraceptive, or combination contraceptive vaginal ring or patch*
  You can start Carmenelle preferably on the day after the last active tablet (the last tablet containing 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 combination 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 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 Carmenelle between 21 and 28 days after having a baby. If you start later than day 28, use a so-called barrier method (for example, a condom) during the first seven days of Carmenelle use.
  If, after having a baby, you have had sex before starting Carmenelle (again), be sure that you are not pregnant or wait until your next period.

- *If you are breast-feeding and want to start Carmenelle (again) after having a baby*
  Read the section on "Breast-feeding", page 6.

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

If you take more Carmenelle than you should

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

If you forget to take Carmenelle

- If you are **less than 12 hours** late taking a tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and then take the following tablets again at the usual time.
- If you are **more than 12 hours** late taking a tablet, the protection against pregnancy may be reduced. The greater the number of tablets that you have forgotten, the greater is the risk of becoming pregnant.

The risk of incomplete protection against pregnancy is greatest if you forget a tablet at the beginning or at the end of the strip. Therefore, you should keep to the following rules (see the diagram on page 9):

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

- **One tablet forgotten in week 1**

Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time and use **extra precautions** for the next 7 days, for example, a condom. If you have had sex in the week before forgetting the tablet you may be pregnant. In that case, contact your doctor.

- **One tablet forgotten in week 2**

Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. The protection against pregnancy is not reduced, and you do not need to take extra precautions.

- **One tablet forgotten in week 3**

You can choose between two possibilities:

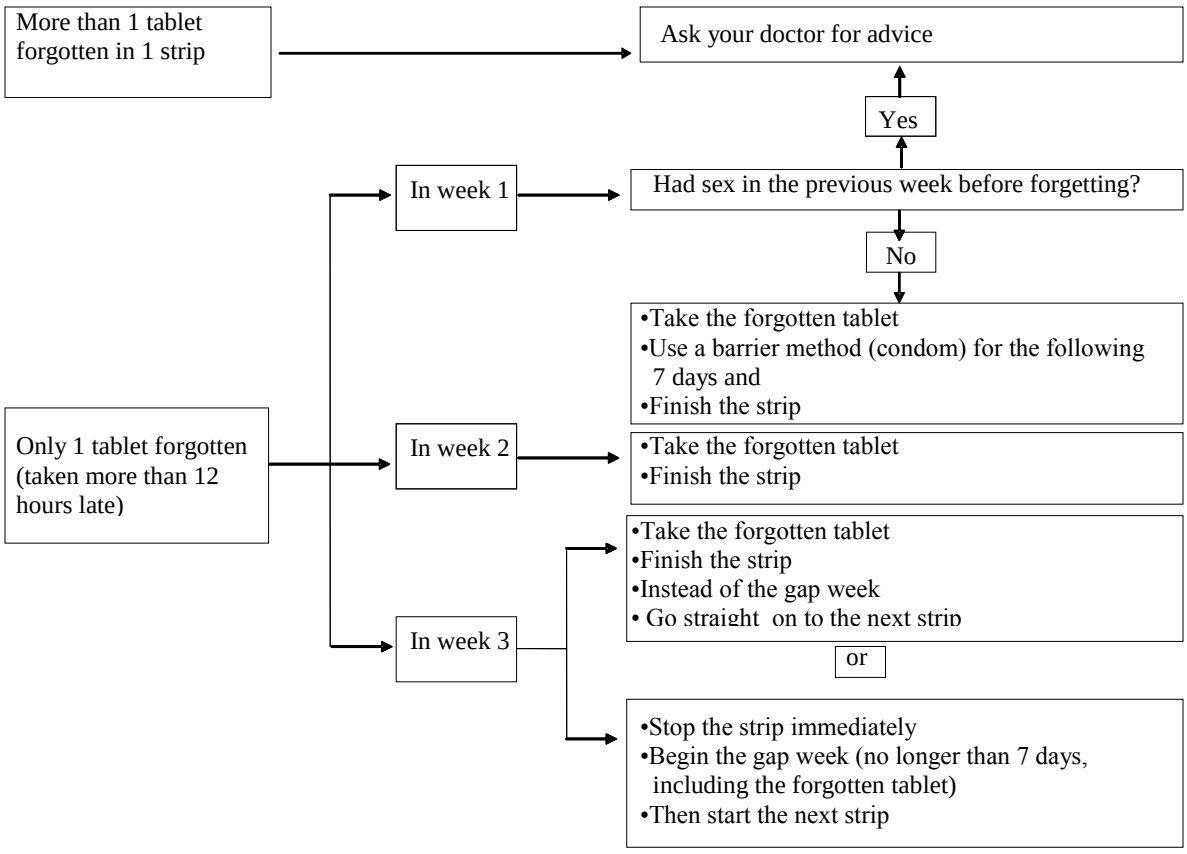
1. Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. Instead of taking the tablet-free period start the next strip .

   Most likely, you will have a period at the end of the second strip but you may have light or menstruation-like bleeding during the second strip.

2. You can also stop the strip and go directly to the tablet-free period of 7 days (**record the day on which you forgot your tablet**). If you want to start a new strip on the day you always start, make the tablet-free period *less than 7 days*.

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

- If you have forgotten any of the tablets in a strip, and you do not have a bleeding during the first tablet-free period, you may be pregnant. Contact your doctor before you start the next strip.



What to do in the case of vomiting or severe diarrhoea

If you vomit within 3-4 hours after taking a tablet or you have severe diarrhoea, there is a risk that the active substances in the pill will not be fully taken up by your body. The situation is almost the same as forgetting a tablet. After vomiting or diarrhoea, take another tablet from a reserve strip as soon as possible. If possible take it *within 12 hours* of when you normally take your pill. If that is not possible or 12 hours have passed, you should follow the advice given under "If you forget to take Carmenelle", page 8.

Delaying your period: what you need to know

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

You might ask your doctor for advice before deciding to delay your menstrual period.

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

If you take the tablets according to the instructions, then your period will begin during *the tablet-free week*. If you have to change this day, reduce the number of tablet-free days (*but never increase them – 7 is the maximum!*). For example, if your tablet-free days normally begin on a Friday, and you want to change this to a Tuesday (3 days earlier) start a new strip 3 days earlier than usual. If you make the tablet-free interval very short (for example, 3 days or less) you may not have any bleeding during these days. You may then experience light or menstruation-like bleeding.

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

If you want to stop taking Carmenelle

You can stop taking Carmenelle 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 Carmenelle and wait for a 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, Carmenelle 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 Carmenelle, 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 Carmenelle".The following is a list of the side effects that have been linked with the use of Drospirenone/Ethinylestradiol.

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

- mood swings
- headache
- abdominal pain (stomach ache)
- acne
- breast pain, breast enlargement, breast tenderness, painful or irregular periods
- weight gain

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

- Candida (fungal infection)
- cold sores (herpes simplex)
- allergic reactions
- increased appetite
- depression, nervousness, sleep disorder
- feeling of "pins and needles", giddiness (vertigo)
- problems with vision
- irregular heart beat or unusually fast heart rate
- high blood pressure, low blood pressure, migraine, varicose veins
- sore throat
- nausea, vomiting, inflammation of stomach and/or intestine, diarrhoea, constipation
- sudden swelling of the skin and/or mucous membranes (e.g. tongue or throat), and/or difficulty swallowing or hives together with difficulty breathing (angioedema), hair loss (alopecia), eczema, itching, rashes, dry skin, oily skin disorder (seborrheic dermatitis)
- neck pain, limb pain, muscle cramps
- bladder infection
- breast lump (benign and cancer), milk production while not pregnant (galactorrhea), ovarian cysts, hot flushes, absence of periods, very heavy periods, vaginal discharge, vaginal dryness, lower abdominal (pelvic) pain, abnormal cervical smear (Papanicolaou or Pap smear), decreased interest in sex
- fluid retention, lack of energy, excessive thirst, increased sweating
- weight loss.

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

- asthma
- hearing impairment
- erythema nodosum (characterized by painful reddish skin nodules)
- erythema multiforme (rash with target-shaped reddening or sores)
- harmful blood clots in a vein or artery for example:
    - in a leg or foot (i.e. DVT)
    - in a lung (i.e. PE)
    - heart attack
    - stroke
    - mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA)
    - blood clots in the liver, stomach/intestine, kidneys or eye.

The chance of having a blood clot may be higher if you have any other conditions that increase this risk (See section 2 for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Carmenelle
Keep this medicine out of the sight and reach and of children.

Store below 30ºC.

Expiry date

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

Do not throw away 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 Carmenelle contains:
- The active substances are ethinylestradiol and drospirenone.
  Each tablet contains 0.20 milligram ethinylestradiol and 3 milligram drospirenone.
- Other ingredients (excipients) are lactose monohydrate, pregelatinised starch (maize), povidone (E1201), croscarmellose sodium, polysorbate 80 (E433), 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 Carmenelle looks like and contents of the pack
- Each blister of Carmenelle contains 21 pink, round film-coated tablets.
- Carmenelle is available in boxes of 1, 2, 3, 6 and 13 blisters each with 21 tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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:

The Netherlands:	Carmenelle 0,02 mg/3 mg filmomhulde tabletten
Austria:	Laurine 0,02 mg/3 mg Filmtabletten
Belgium:	Ethinylestradiol/Drospirenone ELC-Group 0,02 mg/3 mg filmomhulde tabletten
Luxembourg:	Ethinylestradiol/Drospirenone ELC 0,02 mg/3 mg comprimés pelliculés
Germany:	Laurine STADA 0,02 mg/ 3 mg Filmtabletten

Denmark:	Sironelle
France:	Ethinylestradiol/Drospirenone EG 0.02 mg/3 mg comprimé pelliculé
Ireland:	Carmenelle 0.02 mg/3 mg film-coated tablets
Italy:	Chrystelle
Sweden:	Sironelle

This leaflet was last approved in March 2016.