

Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

FLORET® , Tablets

Each tablet contains Ethinylestradiol 0.03 mg and Gestodene 0.075 mg.

Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar.

1. What is the medicine intended for?

Floret is intended for birth control. Each tablet contains two female hormones, estrogen (ethinylestradiol) and progesterone (gestodene).

Therapeutic group: Combined oral contraceptive pills, an estrogen and progesterone combination.

A few important things to know about combined pills:

- When used correctly, combined pills are considered one of the most reliable reversible methods of contraception.
- They slightly increase the risk of thrombosis (blood clots) in the veins and arteries, especially in the first year or when restarting after 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 "Floret and thrombosis (blood clots)")
- Like other contraceptive pills, Floret does not protect you against HIV infection (AIDS) or other sexually transmitted diseases. If you think you are at risk, you should use a condom as well as the pill.

2. Before using the medicine

Before you start taking Floret you should read the information on thrombosis (blood clots) in section 2. It is particularly important to read the part about symptoms of thrombosis (see section 2 "Floret and thrombosis (blood clots)").

Do not use the medicine if:

you have any of the following conditions. 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.

- you are hypersensitive (allergic) to the active ingredients (gestodene or ethinylestradiol) or to any of the other ingredients this medicine contains (see section 6).
- you have (or have ever had) a blood clot in a blood vessel in your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolism, PE) or in other organs.
- 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.
- you are about to have surgery or you will be immobile for a long time (see "Floret and thrombosis (blood clots)").
- you have ever had a heart attack or a stroke.
- 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 a transient ischemic attack (TIA – temporary stroke symptoms).
- you have any of the following diseases that may increase your risk of a blood clot in the arteries:
 - severe diabetes with blood vessels damage
 - very high blood pressure
 - very high levels of fat in the blood (cholesterol or triglycerides)
 - a condition of abnormally high homocysteine
- you have or have ever had an inflammation of the pancreas (pancreatitis) with high levels of fat/triglycerides in the blood.
- you have (or have ever had) a type of migraine called "migraine with aura".
- you have breast cancer or suspected breast cancer.
- you have a cancer of the lining of the womb, cervix or vagina.
- you have a liver tumor (cancerous or non-cancerous).
- you have a liver disease and your liver function is not yet back to normal.
- you have unexplained vaginal bleeding (until a diagnosis is reached by your doctor).
- you are pregnant or could be pregnant.
- you are breastfeeding.
- you have hepatitis C (viral liver inflammation) and are being treated with medicines containing: ombitasvir/paritaprevir/ritonavir, and dasabuvir or glecaprevir/pibrentasvir (see "Drug interactions").

Special warnings regarding the use of the medicine:

Seek immediate medical attention: If you notice possible symptoms 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 lungs (i.e. pulmonary embolism), heart attack or stroke (see "Floret and thrombosis (blood clots)"). For a description of the symptoms of these severe side effects, please see in section 2 "How to identify a blood clot".

Talk to your doctor before taking Floret if any of the following conditions apply to you. You should also consult your doctor if any of the conditions develop, or get worse during treatment with Floret:

- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- if you have systemic lupus erythematosus (SLE – a disease affecting your immune system)
- if you have hemolytic uremic syndrome (a blood clotting disorder causing kidney failure)
- if you have sickle cell anemia (a hereditary disease of the red blood cells).
- if you have elevated blood lipid levels (hypertriglyceridemia) or if you have a family history of this condition. Hypertriglyceridemia has been associated with an increased risk of developing pancreatitis.
- if you are about to undergo surgery or you will be immobile for a long time (see "Floret and thrombosis (blood clots)").
 - if you have recently given birth, you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can use Floret.
 - if you have an inflammation in the veins under the skin (superficial thrombophlebitis).
 - if you have varicose veins.
 - if you have breast nodules, fibrocystic disease of the breast, an abnormal breast X-ray or an abnormal mammogram.
 - if you have severe headaches or epilepsy.
 - if you suffer from depression.
 - if you have gallbladder, heart, or kidney disease.
 - hypertension.
 - diabetes.
 - a metabolic disorder called porphyria, liver problems.
 - brown patches that appear on your face and body like those that occur during pregnancy (chloasma).
 - cancers of the womb (benign (non-cancerous) tumor that grows from the fibrous muscular tissues of the uterine wall).
 - problem wearing contact lenses.
 - migraines.
 - Disturbances of vision.
- Sydenham's chorea (a disease characterized by rapid body movements, uncoordinated jerking movements affecting primarily the face, feet and hands).
- Pemphigoid gestationis (a blistering skin disease that occurs during pregnancy).
- otosclerosis-related hearing loss.
- blood lipid disorders (high or low levels of fat in your blood).
- calcium deficiency with muscle cramps.
- inflammation of the veins (phlebitis).
- swelling of face, eyes, mouth or difficulty breathing.

Psychiatric disorders

Some women using hormonal contraceptives including Floret have reported depression or depressive mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and symptoms of depression, contact your doctor for further medical advice as soon as possible.

Floret and thrombosis (blood clots)

Using a combined hormonal contraceptive such as Floret increases your risk of developing a blood clot compared to the risk in women who are not using such contraceptives. In rare cases, a blood clot can block blood vessels and cause serious problems. Blood clots can develop:

- In veins [venous thrombosis, venous thromboembolism (VTE)].
- In arteries [arterial thrombosis, arterial thromboembolism (ATE)].

Recovery from blood clots is not always complete. Rarely, there may be severe prolonged effects or, very rarely, they may be fatal.

It is important to remember that the overall risk of developing a harmful blood clot due to using Floret is low.

How to identify symptoms of a blood clot

Refer to a doctor urgently if you notice any of the following 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: <ul style="list-style-type: none">pain or tenderness in the leg which may be felt only when standing or walkinga sensation of heaviness in the affected legchange in color of the skin on the leg, for example turning pale, red or blue.	Deep vein thrombosis
<ul style="list-style-type: none">Sudden unexplained breathlessness or rapid breathingsudden cough without an obvious cause, which may bring up bloodsharp chest pain which may increase with deep breathinglight-headedness or dizzinessrapid or irregular heartbeatssevere stomach pain If you are unsure, talk to your doctor or 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

Signs which most commonly occur in one eye:	Retinal vein thrombosis (a blood clot in the eye blood vessel)
<ul style="list-style-type: none">immediate loss of vision orpainless blurring of vision which can progress to loss of vision.	Heart attack
<ul style="list-style-type: none">chest pain, discomfort, pressure, heavinesssensation of squeezing or fullness in the chest, arm or under the breastbonefeeling of fullness, indigestion or choking feelingfeeling of upper body discomfort radiating to the back, jaw, throat, arm and stomachsweating, nausea, vomiting or dizzinessextreme weakness, anxiety or shortness of breathrapid or irregular heartbeats.	Stroke
<ul style="list-style-type: none">sudden weakness or numbness of the face, arm or leg, especially on one side of the bodysudden confusion, trouble speaking or understandingsudden trouble seeing in one or both eyessudden trouble walking, dizziness, loss of balance or coordinationsudden, severe or prolonged headache with no known causeloss of consciousness or fainting with or without seizure. Sometimes, the symptoms of stroke can be very brief with an almost immediate and full recovery, but you still must seek urgent medical attention, as you may be at risk of another stroke.	Blood clot blocking other blood vessels
<ul style="list-style-type: none">swelling and slight blue discoloration of the extremitiessevere sudden pain in your stomach (acute abdomen).	Blood clot blocking other blood vessels

Venous thrombosis

What can happen if a blood clot forms in a vein?

The use of the combined hormonal contraceptives is connected with an increase in the risk of developing blood clots in the veins (venous thrombosis). However, this side effect is rare. It can occur more frequently in the first year of use of a combined hormonal contraceptive.

If a blood clot develops in a vein in the leg or foot it can cause deep vein thrombosis (DVT). If a blood clot travels from the leg and locates in the lung, it can cause a pulmonary embolism.

Very rarely a blood 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 when you restart taking a combined hormonal contraceptive (the same product you took in the past or another) after a break of 4 weeks or more.

After the first year, the risk decreases but will always be slightly higher than if you were not taking a combined hormonal contraceptive.

When you stop taking Floret your risk of developing a blood clot returns to a normal level within a few weeks.

What is the risk of developing a blood clot?

The risk depends on your natural tendency to develop venous thromboembolism (VTE) and on the type of combined hormonal contraceptive you are taking.

The overall risk of developing a blood clot in the leg or lungs (DVT or PE) with Floret is small.

- Out of every 10,000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 women will develop a blood clot each year.
- Out of every 10,000 women who are using a combined hormonal contraceptive that contains levonorgestrel, norethisterone, or norgestimate, about 5-7 will develop a blood clot each year.
- Out of every 10,000 women who are using a combined hormonal contraceptive that contains ethinylestradiol and gestodene such as Floret, about 9-12 will develop a blood clot each year.
- The risk of developing a blood clot will vary according to the medical history (see "Factors that increase your risk of developing a blood clot in a vein" below).

Factors that increase your risk of developing a blood clot in a vein

The risk of developing a blood clot while taking Floret is small, but some conditions will increase this risk.

Your risk will be higher:

- if you are very overweight (BMI over 30 kg/m²)
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g., below the age of 50). In such a case, you may have a hereditary blood clotting disorder.
- if you need to have an operation, or if you are immobile for a long time because of an injury or illness, or if your leg is in a cast. The use of Floret may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop taking Floret, ask your doctor when you can start taking Floret again
- with age (particularly over the age of 35)
- if you gave birth less than a few weeks ago.

The risk of developing a blood clot increases the more risk-increasing conditions you have.

A flight (over 4 hours) may temporarily increase the risk of a blood clot, particularly if you have other risk-increasing conditions.

It is important to tell your doctor if one of the above conditions applies to you, even if you are unsure. Your doctor may decide that you should stop taking Floret.

If any of these conditions changes while using Floret, for example one of your close family members experiences a thrombosis for no known reason or you gain a lot of weight, tell your doctor.

Arterial thrombosis

What can happen if a blood clot forms in an artery?

Like a blood clot in a vein, a blood 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 developing a blood clot in an artery

It is important to note that the risk of a heart attack or stroke due to the use of Floret is very low, but may increase:

- with age (beyond 35 years)
- if you smoke. When using a combined hormonal contraceptive like Floret, it is recommended that you stop smoking. If you are unable to stop smoking and are older than 35 years of age, your doctor may advise you to use a different type of contraceptive.
- if you are overweight
- if you have high blood pressure that is not controlled by medications
- if a member of your immediate family has had a heart attack or stroke at a young age (under the age of 50). In this case, you could also have a higher risk of having a heart attack or a 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 migraine with aura
- if you have a problem with your heart (valve disorders, disturbance of the rhythm called atrial fibrillation)
- if you have diabetes

If you have more than one of these conditions or if one of them are particularly severe, the risk of developing a blood clot may be increased even more.

If any of these conditions changes while using Floret, 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.

Contraceptive pills and cancer

Every woman is at risk of breast cancer whether or not she takes the pills. Breast cancer is rare in women under the age of 40 years, but the risk increases as a woman gets older.

Breast cancer has been found slightly more often in women who take the pills than in women who do not take the pills. If the woman stops taking the pill the result is that 10 years after stopping the pills her risk of breast cancer diagnosis is the same as for a woman who has never taken the pills.

Breast cancer seems less likely to have spread in the body in women who took the pills than in those who did not take the pills.

It is not clear whether the pill causes the increased risk of breast cancer. It may be that women taking the pills are examined more often so that breast cancer is noticed earlier. The risk of finding breast cancer is not affected by how long a woman takes the pills but by the age at which she stops. This is because the risk of breast cancer increases as a woman gets older.

Cancerous tumors in the liver have rarely been reported in long-term users of the pills. Non-malignant liver tumors have been observed in women taking the pill. Discontinuation of the pill may be necessary with sudden or long-term disturbance in liver function. Do not take the pill until liver function has returned to normal.

Some studies suggest that oral contraceptives may increase your risk of cancer of the cervix, although this may be due to differences in sexual behavior rather than to the pill. All women should have regular cervical smear tests. Chronic infection with the Human Papilloma virus (HPV) is the most important risk factor for cervical cancer.

You should consider these possible risks alongside the benefits of taking the pill.

Vision disorders

There have been case reports of retinal thrombosis (closure of the central retinal artery causing sudden, usually nearly complete, loss of vision) with the use of oral contraceptives. Oral contraceptive should be discontinued if there is unexplained partial or complete loss of vision, rapid swelling of an eyeball, double vision or any sudden changes to your eyesight.

Gallbladder Disease

An increased relative risk of gallbladder disease in users of oral contraceptives and estrogens has been reported in some studies.

Bleeding irregularities

As with all the pills, for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use suitable sanitary protection but keeping taking your pills as usual. Irregular vaginal bleeding usually stops once your body has adjusted to the pill (usually after about 3 tablet taking cycles). If it continues, becomes heavier, or starts again, tell your doctor.

If you forget to take a pill and then do not get a bleeding in the pill-free interval, the possibility of pregnancy must be considered.

If you forgot to take one pill (or more), and had unprotected sexual relations, you may be pregnant. Consult the doctor or pharmacist regarding emergency contraceptives.

After using the pills some women may experience amenorrhea (absence of menstrual period) or oligomenorrhea (infrequent or very light menstrual period), especially when such a condition was pre-existent.

Smoking

Tell your doctor if you start smoking while you are taking Floret.

The risk of arterial thrombosis and heart attack or stroke while using Floret increases if you smoke. When using a combined hormonal contraceptive like Floret 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.

Check-ups, follow up, and lab tests Your doctor will examine you before prescribing Floret; the examination should be repeated regularly. Examination frequency and nature must be based on guidelines and practical experience and adjusted for the individual woman. During the examination blood pressure should be measured, and it should include examination of your womb and surrounding organs, breasts, pelvis and abdomen. Your doctor should also note your family history.

A PAP smear must be performed if the patient has been sexually active or if it is otherwise indicated. Before doing blood tests tell the doctor that you are taking the pill because this product may affect the test results.

Drug interactions

If you are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Certain medicines may interfere with the way the pill works. Some medicines may prevent your pill from working and may cause unusual bleeding (bleeding in between periods) and irregular periods. These include:

- medicines used to treat epilepsy (such as phenytoin, primidone, carbamazepine, oxcarbazepine, topiramate)
- some medicines used to treat tuberculosis (rifabutin)
- phenylbutazone, dexamethasone (anti-inflammatory medicines)
- modafinil (for excessive daytime sleeping problems)
- some medicines used to treat HIV/AIDS (protease inhibitors)
- certain tranquilizers and sleeping medicines ("called barbiturates")
- griseofulvin (a medicine used to treat fungal infections)
- medicines that reduce gastrointestinal transit time
- certain antibiotics (such as rifampicin)
- the herbal remedy commonly known as St. John's wort (*Hypericum perforatum*)

You may have to use another method of contraception as well, such as a condom, while you are taking them and for a further 7 days afterwards. Your doctor may instruct you to use these extra contraceptives for even longer. In addition, follow the instructions in "If you forget to take Floret" in section 3 of this leaflet.

St. John's wort (*Hypericum perforatum*): Breakthrough bleeding and unintended pregnancies have been reported in women taking the pill and St. John's wort (*Hypericum perforatum*). If the pill and St. John's wort are used at the same time, a non-hormonal backup method of birth control is recommended such as a condom.

Some medicines may decrease the activity of the liver enzymes. This may cause an increase in the blood levels of the pill ingredients. Examples of these medicines include atorvastatin, indinavir, fluconazole and troleandomycin. Medicines that affect absorption of the pill in your intestines (such as ascorbic acid (vitamin C) and paracetamol) may have a similar effect.

The pill may affect the way that other medicines work or increase the risk of potential side effects. These include some medicines that are broken down by the liver (e.g. cyclosporine, theophylline, corticosteroids) and the medicines flunarizine and lamotrigine.

Do not use Floret if you have hepatitis C (viral liver inflammation) and are taking medicines containing: ombitasvir/paritaprevir/ritonavir, and dasabuvir or glecaprevir/pibrentasvir as this may cause increases in liver function blood test results (increase in ALT liver enzyme). Your doctor will prescribe another contraceptive before you start treatment with these medicines.

Floret can be restarted about 2 weeks after completing treatment with these medicines. See the section "Do not use this medicine if".

To prevent risks or inefficiency caused by interactions with other medicines, consult your doctor or pharmacist before taking any other medicine while you are using Floret.

Pregnancy, breastfeeding and fertility If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine. If you become pregnant, stop taking the pills immediately and consult your doctor. Use another method of contraception, such as a condom, until the pregnancy is confirmed. Small amounts of contraceptive steroids and/or metabolites have been identified in the milk of nursing mothers, and a few side effects on the child have been reported, including jaundice and breast enlargement. The use of the pill is generally not recommended until the nursing mother has completely weaned her child.

Driving and using machines Floret has no known effect on the ability to drive and operate machines.

Important information about some of the ingredients of the medicine Floret contains lactose and sucrose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. This medicine contains less than 1 millimole sodium (23 mg) per tablet, that is to say essentially "sodium free".

Always use the medicine

3. How should you use the medicine Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

About the pack The pack has been designed to help you remember to take your tablets on time. Each pack contains 21 tablets. On the back of the pack, each tablet is marked with the day of the week and an arrow indicating the direction of progression. Take the first pill on the first day of your period according to the day of the week marked on the pack. This will be the day you start with every new pack. Continue taking the tablets in the direction of the arrows until you have used up all the tablets.

The usual recommended dosage is: one tablet, every day, at a fixed time, from the first day of your menstrual bleeding and for 21 consecutive days, followed by a 7-day pill-free break. Your period will usually appear during this break.

Swallow the tablet whole. Do not crush/halve/chew the pill as these actions may interfere with the absorption of the active ingredients of the tablet and thus impair its efficiency. The dosage and treatment regimen will be determined by your doctor only. Do not exceed the recommended dose. Your doctor will decide how long you will take this treatment.

Starting the first pack How to start your first pack when you have not used a hormonal contraceptive in the past month?

Take the first tablet on the first day of your period, this is day one of your cycle – the day when bleeding starts. Your will be protected at once. If you start to take the first tablet on any other day, use another method of contraception as well, such as a condom, for the first 7 pill-taking days. This is only for your first pack. You can take your tablet at any time, but you should swallow your tablet at the same time each day: it is usually easiest to take the tablet before bed or first thing in the morning. Once you have taken all 21 tablets in the pack, stop taking the tablets for 7 days. You will probably bleed during some of these days.

You do not need to use any other form of contraception during the 7-day break provided you have taken all the 21 tablets properly, and provided you start the next pack on time.

The next pack After 7 pill-free days, start your next pack. Do this whether or not you are still bleeding. This way you will always start a new pack on the same day of the week.

Starting after childbirth or pregnancy After a birth, abortion or miscarriage, your doctor will advise you about taking the pill. After a miscarriage or abortion in the first 3 months of pregnancy you can start using Floret immediately.

If you have had a normal delivery without any later complications, and are fully mobile and are not breastfeeding, and you have not had an abortion in months four, five or six of pregnancy, you can start taking Floret 28 days after delivery or abortion. Additional contraception (such as a condom) must be used for the first 7 days of pill-taking. If you have had unprotected sex after day 21, you should not start Floret until your period starts. If you are breastfeeding, the combined pill is not recommended because it can reduce your flow of milk. If you have any questions about starting Floret after childbirth or pregnancy, ask your doctor or pharmacist.

If you are changing to Floret after taking another pill If you are changing to Floret after using another pill, follow your doctor's instructions.

When changing from another 21-day combined estrogen-progesterone pill to Floret, start taking Floret the day after you finish the course of the previous pill.

If you are changing from a 28-day combined estrogen-progesterone pill, start taking Floret the day after you take the last active tablet of the previous pill.

In either of these cases, no bleeding is expected until the end of the first course of Floret. No additional contraception is required in these cases.

Switching from a progesterone-only pill, or injected or implanted contraceptives to Floret: If you are changing from a progesterone-only pill you can stop taking the progesterone-only pill on any day and start taking Floret the next day at the same time. Use an additional form of contraception, such as the condom, for the first seven days of the first pack.

If you are changing from an injectable or implant contraceptive you can start using Floret on the day your implant is removed or the day your next injection is due. Use an additional form of contraception, such as a condom, for the first seven days of the first pack.

If there is no bleed after you finish the pack If you have taken all your pills correctly it is

unlikely you are pregnant. However, you should make sure that you are not pregnant before you start your next pack.

If you have accidentally taken a higher dose of Floret Taking too many tablets of Floret might cause nausea, vomiting, breast tenderness, dizziness, abdominal pain, and drowsiness/fatigue. Bleeding may occur in some women. In case of an overdose, contact your doctor or pharmacist.

If a child has accidentally swallowed the medicine, immediately proceed to a doctor or hospital emergency room and bring the package of the medicine with you.

If you forget to take Floret: If you are less than 12 hours late in taking your pill, take a tablet as soon as you remember, and carry on taking your next tablets as usual. If you are more than 12 hours late in taking your pill, take the last missed tablet as soon as you remember and continue taking the rest of the tablets as usual, even if it means taking 2 tablets in one day. Continue to take Floret as usual until you finish the pack, and use extra contraception (condom, for instance) for the next 7 days. If the 7 days in which you require extra contraception run beyond the end of the present pack, start the next pack the day after you have taken the last tablet in the present pack, without a break. In this case, a vaginal bleed (period) will occur only at the end of the second pack. If you do not get a period when you finish the second pack, consult your doctor immediately before starting the new pack.

If you are suffering from diarrhea or vomiting The pill may not work. If the diarrhea or vomiting happens within 4 hours after taking the pill, follow the instructions under "If you forget to take Floret – If you are less than 12 hours late in taking your pill". The extra tablet should be taken from a backup pack. If the vomiting or diarrhea happens more than 4 hours after taking the pill, continue taking it as usual, but you may not be protected from the first day of vomiting or diarrhea. Use another contraception method, such as a condom, during the period of diarrhea and vomiting until you start your next pack.

If you want to stop taking this medicine You can stop using Floret any time. If you do not want to get pregnant, consult your doctor about other effective means of contraception.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them. If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of Floret may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

If one or more of the side effects occur, especially if it is severe or prolonged, or if you feel any change in your health and are concerned that it may be due to using Floret, refer to your doctor.

An increased risk of blood clot formation in the veins (venous thromboembolism (VTE)) or in the arteries (arterial thromboembolism (ATE)) exists in all women using combined hormonal contraceptives. For more detailed information see section 2 "Before using the medicine".

Refer to your doctor straight away if you experience any of these symptoms:

- Swelling of the face, lips or throat which makes it difficult to swallow or breathe as well as itching and rash. This could be a sign of a severe allergy to Floret.
- Severe sudden onset of rash
- Severe headache or migraine
- Difficulty in seeing or speaking
- Pain or swelling in the legs
- Fainting
- Pain in the chest or stomach
- Shortness of breath
- Numbness in an arm or leg
- Coughing with blood
- Breast lumps.

Your doctor will probably stop your Floret treatment if:

- jaundice occurred
- blood pressure increased
- You have any condition that can get worse with pill use and it shows signs of getting worse (see section 2 "Before using this medicine")

If you have bleeding while you are taking the tablets You may at first have some inter-menstrual bleeding or staining while you are taking your tablets, but your periods should settle down after a few months. However, if the bleeding is heavy, continuous or keeps returning, consult your doctor.

Floret may cause some minor side effects. Tell your doctor if the following symptoms bother you:

Very common side effects (effects that occur in more than 1 in 10 users):

- Headache, including migraines
- Breakthrough bleeding/spotting

Common side effects (effects that occur in 1-10 out of 100 users):

- Abdominal pain/stomach cramps
- Nausea and vomiting
- Changes in body weight
- Changes in sexual drive
- Depressive moods, nervousness
- Dizziness
- Tender breasts or discharge from your breasts
- Acne
- Irregular bleeding or painful bleeding or missed bleeds
- Fluid retention or bloating
- Changes in vaginal discharge, vaginal infections such as thrush