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 the 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 contraception.
Each tablet contains two female hormones, estrogen (ethinylestradiol) and progestogen (gestoden).

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

Several 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 (ethinylestradiol or gestodene) 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 off your feet 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 taking medicines containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see "Drug interactions").

Special warnings regarding the use of the medicine:

<u>Seek immediate medical attention:</u>
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 lung (i.e. pulmonary embolism), a heart attack or stroke (see "Floret and thrombosis (blood clots)").
For information about the symptoms of these serious side effects, please see in section 2 "How to identify a blood clot".

If you have one of the following conditions, consult your doctor before taking Floret. 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 levels of fat in the blood (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 off your feet 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).
- Fibroids of the womb (benign (noncancerous) 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.
- If you experience symptoms of angioedema, such as swollen face, tongue and/or throat and/or difficulty swallowing or rash (hives) potentially with difficulty breathing, contact a doctor immediately. Products containing estrogens may cause or worsen the symptoms of hereditary or acquired angioedema.

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 a blood clot 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 developing a harmful blood clot due to using Floret is low.

How to recognize symptoms of a blood clot?
Refer to a doctor urgently if you notice any of the following symptoms.

Do you experience one or more 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:	Deep vein thrombosis

• pain or tenderness in the leg which may be felt only when standing or walking • a sensation of warmth in the affected leg • change in color of the skin on the leg, for example turning pale, red or blue.	
• 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 • light-headedness or dizziness • rapid or irregular heartbeats • severe stomach pain If you are unsure, talk to your 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 a blood vessel in the eye)
• chest pain, discomfort, pressure, heaviness • sensation of squeezing or fullness in the chest, arm or under 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 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.	Stroke
• swelling and slight blue discoloration of an extremity • severe sudden pain in the stomach (acute abdomen).	Blood clot blocking other blood vessels

Blood clots in a vein

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 forms in a vein in the leg or foot it can cause deep vein thrombosis.
- If a blood clot travels from the leg and lodges 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 as before or a different product) 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 normal 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 the type of combined hormonal contraceptive you are taking.
The overall risk of a blood clot in the leg or lungs (deep vein thrombosis or pulmonary embolism) with **Floret** is small.
- Out of 10,000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 women 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 ethinylestradiol and gestodene such as **Floret**, about 9-12 will develop a blood clot in a year.
- The risk of developing a blood clot will vary according to the medical history (see "Factors that increase your risk of a blood clot in a vein" below).

Factors that increase your risk of a blood clot in a vein
The risk of a blood clot with **Floret** is small, but some conditions will increase the risk.
Your risk is higher:
- if you are overweight (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 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 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 increasing age (particularly over the age of 35)
- if you gave birth a few weeks ago.

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

Air travel (over 4 hours) may temporarily increase the risk of a blood clot, particularly if you have other risk factors.

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 **Floret** needs to be stopped.

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.

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 **Floret** is very small, but can increase:

- with increasing age (beyond 35 years)
- **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.
- if you are overweight
- if you have high blood pressure that is not controlled by medication
- 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 is particularly severe, the risk of developing a blood clot may be increased even more.

If any of these conditions change 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, 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 a 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 when it was found 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 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 contraceptives 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 keep 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 withdrawal 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 intercourse, you may be pregnant. Consult the doctor or pharmacist about emergency contraception.

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 you have a blood test, 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 tranquillizers 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)

If you are taking one of the above medicines, you should use another method of contraception as well, such as a condom, while 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 forgot 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. 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, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir as these products 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 section "Do not use the medicine if".

To prevent risks or inefficiency caused by interactions with other medicines, consult the doctor of 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 the doctor or pharmacist before taking this medicine. If you become pregnant, stop taking the pills immediately and consult the 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 use 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 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to 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 blister pack contains 21 tablets. Each tablet is marked on the blister 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 blister. This will be the day you start for every new pack.
Continue taking the tablets in the direction of the arrows until you have used up all the tablets.
The usual dosage is generally: 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 with some water if necessary. 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 manner of treatment will be determined by the 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. You 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 the 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 blister pack

After 7 pill-free days, start your next blister pack. Do this whether or not you are still bleeding. This way you will always start a new blister 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 a condom), for the first 7 days of the first blister 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 7 days of the first blister pack.

If there is no bleed after you finish the blister 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 blister pack.

If you have accidentally taken a higher dosage 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 a hospital emergency room and bring the package of the medicine with you.

If you forgot 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 blister 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 blister pack, start the next blister 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 blister pack. If you do not get a period when you finish the second pack, consult your doctor immediately before starting the new blister 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 forgot 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 diarrhea and vomiting until you start your next blister 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 <u>each time</u> 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. <u>Side effects</u>
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 you suffer from a side effect, 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 a doctor.

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

Refer to a 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.

Serious side effects
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 rash (hives) potentially with difficulty breathing (see also "Special warnings regarding the use of the medicine").

The 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 the medicine")

If you have bleeding while you are taking the tablets
You may at first have some breakthrough bleeding or spotting 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 a doctor.

Floret may cause some minor side effects. Tell the 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.

Uncommon side effects (effects that occur in 1-10 out of 1,000 users):
- Changes in appetite
- Rash, brown patches on the face and body like those that occur in pregnancy (chloasma), itching
- Hair thinning or unusual hairiness
- Increase in blood pressure
- Changes in lipid levels in the blood
- Abdominal cramps, bloating.

Rare side effects (effects that occur in 1-10 out of 10,000 users):
- Severe allergic reactions including angioedema and urticaria (swelling of skin accompanied by itching and hives)
- Glucose intolerance
- Problems with using contact lenses

- Erythema nodosum
- Decrease in serum folate levels
- Cholestatic jaundice (abnormal bile flow in the liver causing yellowing of the skin)
- Harmful blood clot in a vein or artery, for example:
  - in a leg or foot (deep venous thrombosis)
  - in a lung (pulmonary embolism)
  - heart attack
  - stroke
  - mini-stroke or temporary stroke-like symptoms, known as a transient ischemic attack
  - blood clots in the liver, stomach/intestine, kidneys.

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

Very rare side effects (effects that occur in less than 1 in 10,000 users):
- Harmful blood clots in a vein or artery for example, in the eye.
  The chance of having a blood clot may be higher if you have any of the other conditions that increase this risk (see section 2 for more information about conditions that increase the risk of blood clots and the symptoms of a blood clot).
- Gallbladder disease (including gallstones)
- Pancreatitis (inflammation of the pancreas), a blood disorder called hemolytic uremic syndrome (a disorder where blood clots cause kidney failure)
- Exacerbation of systemic lupus erythematosus (an inflammatory disease which can affect many parts of the body, including the skin, joints and internal organs), porphyria, and chorea (a movement disease)
- Inflammation of the optic nerve (may lead to partial or complete loss of vision)
- Aggravation of varicose veins
- Ischemic colitis (inflammation due to inadequate blood flow to large intestine)
- Benign liver tumors
- Cancer of the liver
- Fever and rash of the face, arms, and legs.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** store in the original package, below 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, this medicine also contains:
Lactose monohydrate, sucrose, maize starch, calcium carbonate, talc, macrogol 6000, povidone, titanium dioxide (E171), silica colloidal anhydrous, magnesium stearate, sodium calcium edetate, quinoline yellow (E104).

What the medicine looks like and what the package contains:
Round, biconvex, yellow tablets.
The tablets come in blister packs of 21 tablets. Each package contains 1, 3 or 4 blisters. Not all package sizes may be marketed.
Revised in September 2023 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:
140-57-31528-00

Manufacturer and registration holder: Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel