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 this medicine

Read this entire leaflet carefully before using this 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. is similar

Essential information about combined hormonal contraceptives and about the medicine

• When used properly, combined hormonal contraceptives are considered one of the most reliable reversible methods of contraception. They slightly increase the risk of a blood clot in the veins and arteries, particularly in the first year or when restarting a combined hormonal contraceptive after a break of 4 weeks or more.

after a break of 14 Weeks of more.

You must be alert and refer to a doctor if you think you have symptoms of a blood clot (see in section 2 "Blood clots").

If taken in the long term, contraceptive pills may reduce your risk of ovarian and uterine cancer.

reduce your risk of ovarian and uterine cancer.
Contraceptive pills do not protect against sexually
transmitted diseases such as AIDS or chlamydia,
only a condom can help with this.
This medicine may increase your risk for effects
such as blood clots and breast cancer.
Contraceptive pills may not be suited for some
women due to their medical condition. Please

read the leaflet in order to make sure that Floret read the leaflet in order to make sure that Floret is right for you.

To prevent pregnancy, it is important to take Floret according to the instructions and start a new package on time. Please make sure you understand what you have to do if you forget a tablet or if you think you are pregnant.

1. What is the medicine intended

Floret is intended for contraception.
Therapeutic group: Floret belongs to a group of medicines called combined pills (contraceptive pills) that contain 2 types of female hormones: estrogen (ethinylestradiol) and progestogen (gestodene).
These hormones prevent pregnancy in 3 ways: by preventing the release of an egg from the ovary, thickening of the secretion from the cervix, which makes it more difficult for the sperm to penetrate the uterus and preventing thickening of the uterus lining required for the implantation of the egg.

• When used properly, contraceptive pills are considered one of the most reliable
• reversible methods of contraception.

reversible methods of contraception

- Contraceptive pills do not interrupt sex.
 Contraceptive pills usually make your periods regular, lighter and less painful.
 Contraceptive pills may relieve premenstrual symptoms.

2. <u>Before using the medicine</u> Do not use the medicine if:

you are hypersensitive (allergic) to gestodene or ethinylestradiol or to any of the other ingredients this medicine contains (see section 6). you are pregnant or there is a chance

you are pregnant or there is a chance you might be pregnant.
 you suffer or have suffered in the past from a blood clot in the blood vessels in your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolism, PE), the heart (heart attack) or in other organs.
 you know you have a blood clotting disorder (for example, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor 5 Leiden or antiphospholipid syndrome).

deficiency, protein S deficiency, antithrombin-III deficiency, Factor 5 Leiden or antiphospholipid syndrome).

•you have to undergo surgery or if you are immobile for a long time (see "Blood clots" in section 2).

•you have suffered in the past from a heart attack or stroke.

•you suffer or have suffered in the past from 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 suffer from any of the following diseases which may increase your risk of a blood clot in the arteries:

Severe diabetes with blood vessels damage

• Very high blood pressure

• Very high blood pressure

• Very high blood ilipid levels (cholesterol or triglycerides)

• A medical condition characterized by high blood homocysteine levels (hyperhomocysteinemia)

• you suffer or have suffered in the past from a type of migraine called migraine with aura.

• you have suffered in the past from a severe liver disease, and you have

you have suffered in the past from a

severe liver disease, and you have been told by the doctor that your liver functions are not yet back to you suffer or have suffered in the past from liver tumors.
You have hepatitis C and are taking

the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir (see also in section "Drug

If you suffer from one of the conditions mentioned above, or if one of them appears for the first time, stop treatment and tell the doctor. The doctor will talk with you about other contraceptives that may be more suitable for you. Special warnings regarding the use of the

Special warnings regarding the use of the medicine:

Before you start taking Floret, read the information regarding blood clots further in this section. It is especially important to read what are the symptoms of a blood clot as detailed in section 2 "Blood clots".

It's important that you understand the advantages and disadvantages of taking contraceptive pills before you start taking them, or when deciding whether to carry on taking them. Although contraceptive pills are suitable for most healthy women, they aren't suitable for everyone. Tell your doctor if you have any of the medical conditions or risk factors mentioned in this leaflet. If you need a blood test, notify the doctor you are taking a contraceptive pill, since combined contraceptive pills can affect the results of

When should you refer to the doctor?

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 lungs (i.e. pulmonary embolism), heart attack or stroke (see in section 2 "blood clots").

For a description of the symptoms of these severe side effects. of these severe side effects, please see in section 2 "How to

identify a blood clot" Some of the conditions mentioned below may worsen while taking contraceptive pills, or they may indicate that Floret is not suitable for

you. You may be able to use Floret but it will require closer monitoring by your doctor. Before using Floret, tell the doctor if one of the following conditions applies to you, develops or worsens while taking Floret. r worsens while taking Floret.

b If you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease) lify you have systemic lupus erythematosus (SLE - a disease affecting your immune system) lify you have hemolytic uremic syndrome (a blood clotting disorder causing kidney failure) lify ou have sickle cell anemia (a hereditary disease of the red blood cells)

cells)

cells)

If you are suffering from an inflammation of the pancreas (pancreatitis)

If you suffer from elevated blood lipid levels (hypertriglyceridemia) or if you have a family history of this condition. Hypertriglyceridemia has been associated with an increased rich of developing pengredities.

been associated with an increased risk of developing pancreatitis If you need to undergo surgery, or you are immobile for a long time (see "Blood clots" in section 2) If you have recently given birth, you are at an increased risk of blood other Carellity surders at the long the section 2.

are at an increased risk of blood clots. Consult your doctor as to how soon after delivery you can start taking Floret
If you are suffering from an inflammation in the veins under the skin (superficial thrombophlebitis)
If you suffer from varicose veins
If you have diabetes
If you or a close family member
have ever had heart or circulation

pressure
If you or a close family member
have ever had blood clotting
problems
If you suffer for

problems
If you suffer from a hereditary
disease called porphyria

alsease called porphyria
If you are obese
If you suffer from migraines
If you have any illness that
worsened during pregnancy or
during previous use of contraceptive
pills (see section 4 "Side effects")

Using a combined hormonal contraceptive, such as Floret, increases your risk of developing a blood clot compared with not using one. In rare cases, a blood clot can block blood vessels and

cases, a blood clot can block blood vessels and cause severe problems. Blood clots can develop:
• In veins (a condition called "venous thrombosis", "venous thromboembolism" or VTE).
• In arteries (a condition called "arterial thrombosis", "Interior thrombosmos called "arterial thrombosis",

"arterial thromboembolism" or ATE).

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

It is important to remember that the overall

risk of having a harmful blood clot due to Floret is small.

How to identify a blood clot

Seek urgent medical attention if you notice one of the following signs or symptoms. Are you experiencing any of these signs?

Deep vein

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 or increased warmth in the affected lag. affected leg change in color of the skin on the leg e.g., turning pale, red or blue

Sudden unexplained shortness of breath or rapid embolism breathing
Sudden cough without an obvious cause, which may bring up blood
Sharp chest pain which increases with deep breathing

Severe light-headedness o

Rapid or irregular heartbeat Severe stomach pain If you are unsure, talk to the doctor as some of

the 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

Symptoms which most commonly occur in one eye:
Sudden loss of vision or
Painless blurring of vision which can progress to loss

· Chest pain, discomfort,

Indigestion

Upper body discomfort radiating to the back, jaw, throat, arm and stomach

Sweating, nausea, vomiting or dizziness

or dizziness Extreme weakness, anxiety or

Rapid or irregular heartbeat Sudden weakness or numbness of the face, arm or leg, especially on one side of

the body Sudden confusion, difficulty

speaking or understanding
Sudden difficulty seeing in one
or both eyes
Sudden difficulty walking,
dizziness, loss of balance or

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 still must seek urgent medical attention, as you may be at risk of another stroke.

Swelling and slight blue discoloration of the

If you are suffering from any of these conditions, refer to the doctor immediately. Stop taking Floret until instructed otherwise by the doctor. In the meantime, use another method of contraception, such as a condom.

Blood clots in a vein What could happen if a blood clot forms

The use of combined hormonal contraceptives

• The use of combined hormonal contraceptives has been associated with an increase in the risk of blood clots formation in the vein (venous thrombosis). However, these side effects are rare and occur mainly 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 could cause deep vein thrombosis (DVT).
• If a blood clot travels from the leg and reaches the lung, a pulmonary embolism could form.
• Rarely, a blood clot may form in a vein in another organ such as the eve (retinal vein thrombosis).

organ such as the eye (retinal vein thrombosis)

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 medicine or a different medicine) 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 using a combined hormonal contraceptive.

When you stop using 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

What is the risk of developing a blood

The risk depends on your natural risk of developing 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

is smail.

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 gestodene such as **Floret**, between about 9-12 women will

develop a blood clot in a year.

The risk of developing a blood clot will vary according to your personal medical history (see "Factors that increase your risk of developing a

Factors that increase your risk of developing a blood clot in a vein The risk of developing a blood clot with Floret is small but certain conditions will increase the risk. Your risk is higher:

risk. Your risk is higher:

if you are very overweight (BMI over 30 kg/m²)

if a member 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 undergo surgery, 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 using the medicine again with age (particularly over the age approximately 35) if you gave birth within the past few weeks

The risk of developing a blood clot increases if more of these conditions apply to you.

A flight (over 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 the doctor if one of these conditions are increased.

It is important to tell the doctor if one of these conditions applies to you, even if you are unsure. The doctor may decide that you should stop taking Floret, if one of the conditions listed above changes while using Floret, for example if one of your close family members suffers from thrombosis

for an unknown reason or if you gain a lot of weight, tell the doctor.

Blood clots in an artery What could happen if a blood clot forms in an artery? Like a blood clot in a vein, a blood clot in

the artery may cause severe problems. For example, it may cause a heart attack or a

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 that increase

very low, but may increase:

•with age (beyond about 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 gave your dector may advise 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 if a member of your immediate family has had a heart attack or stroke at a young age (less than about 50 years). In such case, you may also have a higher risk of having a heart attack or a stroke

if you, or a member of your immediate family, have high blood lipid levels (cholesterol or triglycerides) if you suffer from migraines, especially

ringialie with adia if you have a heart function problem (a heart valve disorder, a heart rhythm disturbance called atrial fibrillation)

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 even

If one of the conditions listed above changes while using **Floret**, for example, if you start smoking, a close family member suffers from thrombosis for an unknown reason or if you gain a lot of weight, tell your doctor.

Contraceptive pills and cancer
While high-dosage contraceptive pills reduce the risk of developing ovarian and uterine cancer in long term use, it is unclear whether low-dosage contraceptive pills, such as Floret, will lead to the same protective effect. However, it also seems that taking contraceptive pills slightly increases the risk of cervical cancer - although this may be due to having sex without a condom rather than the use of contraceptive pills. It is recommended for all women to routinely have a Pap test performed.

performed.

If you suffer or have suffered in the past from

If you suffer or have suffered in the past from breast cancer, it is recommended not to use contraceptive pills. Contraceptive pills slightly increase your risk of breast cancer, the risk exists as long as you take contraceptive pills, but returns to normal within 10 years of stopping it. Since breast cancer is rare in women under 40 years of age, the number of additional cases of women diagnosed, who take or have recently taken contraceptive pills, is small. For example:

Out of 10,000 women who have never taken contraceptive pills, approximately 16 will have

Out of 10,000 women who have never taken contraceptive pills, approximately 16 will have breast cancer by the time they are 35 years old.

Out of 10,000 women who took contraceptive pills for 5 years in their early twenties, approximately 17-18 will have breast cancer by the time they are 35 years old.

Out of 10,000 women who have never taken contraceptive pills, approximately 100 will have breast cancer by the time they are 45 years old.

Out of 10,000 women who took contraceptive pills for 5 years in their early thirties, approximately 110 will have breast cancer by the time they are 45 years old.

Your risk of having breast cancer increases:

Your risk of naving breast cancer increases:

if you have a family member (mother, sister or
grandmother) that had breast cancer.

if you suffer from severe obesity.

Refer to the doctor immediately if you notice
changes in your breasts, such as dimpled
skin, changes in the nipple or if you notice or
feel lumps.

Taking contraceptive pills has been associated with liver diseases, such as jaundice and non-cancerous liver tumors, but these cases are rare. Rarely, contraceptive pills have been associated with certain types of liver cancer

in women who have taken the medicine for a

Refer to the doctor immediately if you experience a severe stomach pain of yellowing of the whites of the eyes (jaundice)

Some women using hormonal contraceptives including **Floret** have reported depression or

depressive mood. Depression can be serious

and sometimes lead to suicidal thoughts. If

You may need to stop using Floret

Psychiatric disorders

the time they are 45 years old.

Contraceptive pills and cancer

or a stroke

"migraine with aura'

if you have diabetes

blood clot in a vein" in section 2

extremities vere stomach pain

coordination

shortness of breath

pressure or heaviness Sensation of squeezing or fullness in the chest, arm or below the breastbone Fullness, choking feeling or

(e.g., a common cold).

of vision

indigestion

you experience mood changes and symptoms of depression, contact your doctor for further medical advice as soon as possible.

medical advice as soon as possible.

Smoking
If you smoke, inform the doctor before commencing treatment with this medicine.
The risk of arterial thrombosis and serious cardiovascular side effects associated with contraceptive pills, increases with age. This risk is higher in women who smoke many cigarettes, especially if they are over 35 years of age. Therefore, it is recommended not to smoke while using a contraceptive pill.
If you are unable to stop smoking and you are over 35 years of age, your doctor may recommend you use a different type of contraception.

Tests and follow up.

Retinal vein

thrombosis

(blood clot in

Heart attack

Stroke

Blood clots

blocking other blood

Tests and follow up

• Before you start using a contraceptive pill, the doctor will ask you about your and your family's medical history, check your blood pressure and rule out the possibility of you being pregnant.

• Additional tests, such as a breast examination, may be necessary, but only if you need to have these tests performed or if you have any special concerns.

concerns.

During the course of treatment, you should have regular check-ups with your doctor, including a Pap test.

Check every month if there have been changes in your breasts and nipples. Tell the doctor if you notice or feel any change such as lumps or dimnles in the skin

dimples in the skin. dimples in the skin. Before surgery, make sure the doctor knows that you are taking Floret. You may be asked to stop taking the pill 4-6 weeks before the surgery. This is to lower the risk of a blood clot (see "Blood clots" in section 2). The doctor will

instruct you when you can resume taking the **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.

medicines and nutritional supplements, tell the doctor or pharmacist.

Tell the doctor or pharmacist.

Tell the doctor or pharmacist especially if you are taking any of the following medicines which may affect Floret levels in the blood and thereby impair its activity:

*medicines for treatment of epilepsy such as barbiturates, primidone, phenytoin, carbamazepine, oxcarbazepine, topiramate

*certain medicines for treatment of AIDS (HIV) and hepatitis C (called protease inhibitors) such as ritonavir, neffinavir, nevirapine.

*griseofulvin for the treatment of fungal infections

*CYP3A4 protein inhibitor such as itraconazole, voriconazole and fluconazole (for treatment of fungal infections) and macrolide antibiotics (such as erythromycin) which may elevate estrogen and/ or progestogen levels in the blood.

*certain antibiotics for treatment of infectious diseases such as rifampicin

diseases such as rifampicin

the herbal preparation St. John's wort (hypericum) for treatment of depressive mood

etoricoxib (anti-inflammatory and analgesic)

medicines that may have increased concentrations in the blood when used with Floret – ciclosporin, transiting the population tizanidine, theophylline

medicines that may have decreased concentrations in the blood when used with Floret – Lamotrigine

If you are taking any of the above-mentioned medicines, Floret may not be suitable for you and you will need to use an additional contraceptive for a while. The doctor or pharmacist will instruct you if this is necessary

contraceptive for a while. The doctor or pharmacist will instruct you if this is necessary and for how long.

Additionally, it is recommended that you check the leaflets of the medicines you are taking to see if they can be used concomitantly with hormonal contraceptives.

In addition, Floret may also affect the efficacy of other medicines. Your doctor may adjust the dosage of the medicines you are taking concomitantly with Floret.

Do not use Floret if you have hepatitis C and are taking medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir as this may cause an increase in liver function blood test results (increase in ALT liver enzyme). Your doctor will prescribe another type of contraception before starting freatment with these medicinal products. Floret can be restarted approximately 2 weeks after completion of treatment. See section "Do not use the medicine it").

Use of this medicine and food Use of this medicine and food
The medicine can be taken on an empty stomach or with food.

Pregnancy and breastfeeding
Do not use Floret if you are pregnant.
If you think you might be pregnant, take a pregnancy test before you stop taking the medicine.

medicine. Using Floret while breastfeeding may decrease breast milk volume and alter its composition. Very small amounts of the active ingredients are excreted into breast milk, these quantities may affect the baby, especially during the first 6 weeks after childbirth. If you are breastfeeding, your doctor will advise If you are breastfeeding, your doctor will advise you not to take **Floret**. The doctor could help you choose an alternative method of contraception.

Breastfeeding may not stop you getting

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 this medicine

Floret contains lactose and sucrose. If you have been told by the doctor that you have an intolerance to certain sugars, consult the doctor before starting treatment with Floret.

3. How to use this medicine Always use this 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. The dosage and manner of treatment will be determined by the doctor only. The usual recommended dosage is one tablet per day, at the same time, for 21 days. After 21 days of taking the tablets, take a 7-day break.

Do not exceed the recommended dose.

Method of administration

Swallow the pill with some water. Do not crush/halve/chew the pill as these actions may interfere with the absorption of the active ingredients of the pill and thus impair its efficacy. **Duration of treatment**

Duration of treatment
Take Floret every day for 21 days.
A Floret package has 21 tablets. Each tablet
is marked on the blister with the day of the
week and an arrow indicating the direction of
progress. Start by taking the tablet marked
with the correct day of the week. Continue
taking the tablets in the direction of the arrows
until you finish the package until you finish the package.

Take a 7-day break

Take a 7-day break
After 21 days of taking the tablets, take a
7-day break. So, if you took the last tablet of
the package on a Friday, take the first tablet
of the next package on the Saturday of the
following week. Within a few days of taking the
last tablet, you will have menstrual bleeding. The bleeding may still not have stopped when you start a new package of pills. There is no need for extra contraception during the 7-day break, if you have taken the tablets as per the instructions and started the

new package on time Start a new package

Start a new package - even if the menstrual bleeding has not yet stopped. Always start a new package on time. As long as you use Floret as per the instructions, you will always start a new package on the same day of the Starting to use Floret

Taking Floret for the first time or after discontinued use It is recommended to take the first tablet on the first day of menstrual bleeding. This way, you will have contraceptive protection starting from the first tablet.

Switching to Floret after using another contraceptive pill

If you are currently taking a pill of a 21-pill package: start Floret a day after you have finished taking the other contraceptive pill. This

way you will have contraceptive protection from the first tablet. Menstrual bleeding will occur

only after finishing a Floret package.

If you are currently taking a pill of a 28-pill package: start Floret the day after taking the last active tablet from the other package. This way, you will have contraceptive protection from the first tablet. Menstrual bleeding will only from the first tablet. Menstrual beleding will only occur after you finish the Floret package. If you are taking a progestogen—only pill (POP): start taking Floret on the first day of menstrual bleeding, even if you have already taken a progestogen pill that day. This way you will have immediate contraceptive protection.

will have immediate contraceptive protection.

Starting Floret after a miscarriage or an abortion
If you have had a miscarriage or an abortion during the first three months of pregnancy, your doctor may instruct you to take Floret immediately, and in this case you will have contraceptive protection from the first tablet. If you have had a miscarriage or an abortion after the third month of pregnancy, consult the doctor.

You may need to use an additional contraceptive

You may need to use an additional contraceptive method such as a condom for a short time. method such as a condom for a short time. Using contraceptives after childbirth If you have given birth recently, the doctor will instruct you to take Floret 21 days after childbirth provided that you are completely mobile. There is no need to wait for the menstrual bleeding. You should use an additional contraceptive, such as a condom, until you start taking Floret and during the first 7 days of use.

If you have accidentally taken a higher dosage
It is unlikely that taking more than one
tablet will cause damage, however nausea,
vomiting or vaginal bleeding may occur. This
bleeding can occur in girls who have not yet
started to menstruate and have accidentally
taken the medicine. Consult the doctor if you

experience one of these symptoms.

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you. If you forgot to take the medicine

If the delay in taking one tablet is less than 12 hours, take the tablet as soon as possible and continue taking the rest of the tablets as usual. It may mean taking two tablets on the same day. Do not worry - your contraceptive protection has not been impaired.

If the delay in taking one tablet is more than 12 hours, or you forgot more than one tablet, your contraceptive protection may have been impaired.

Take the last tablet you forgot as soon as possible, even if it means taking two tablets together. If you forgot previous tablets, leave them in the package.

Continue to take one tablet a day for the next 7 days at the usual time

days at the usual time.
If you finish a package during these 7 days, start a new package without taking a 7-day break. You probably will not have menstrual bleeding until after you finish the second package, but there is no need to worry. If you have finished the second package and menstrual bleeding has not yet occurred, perform a pregnancy test before starting another package.
Use an additional contraceptive method, such as a condom, during the 7 days after missing a tablet.

as a condon, using the 7 days after missing a tablet.

If you have missed one or more tablets from the first week of the package (days 1 to 7) and you had sex during that week, you might be pregnant. Consult the doctor as soon as possible. The doctor will advise you regarding emergency contraception. If you forgot to take a tablet, and menstrual bleeding does not occur during the following break days, you might be pregnant. Contact the doctor as soon as possible, or perform a

home pregnancy test.

In the event of vomiting or diarrhea If you suffer from vomiting or acute diarrhea within 4 hours of taking the tablet, there is no absolute guarantee that the daily tablet will be completely absorbed through the gastrointestinal tract.

If you get better within 12 hours of taking

If you get better within 12 hours of taking Floret, follow the instructions in section "If you lost a tablet", which describes how to take

another tablet. If you suffer from vomiting or diarrhea for more

alternative contraception.

Missed a menstrual bleeding - could you

Missed a menstrual bleeding - could you be pregnant?
Occasionally, you may not have menstrual bleeding. This could indicate that you are pregnant, but it is very unlikely if you have taken the tablets as per the instructions. Start the next package at the proper time. If you think there is a chance you are pregnant (for example, if you missed a tablet or you took other medicines concomitantly), or if you miss another menstrual bleeding, you should do a home pregnancy test. If you are pregnant, stop taking Floret and refer to the doctor.

When you are interested in becoming pregnant if you are planning to conceive, it is recommended to use another method of contraception after stopping Floret until you have menstrual bleeding. Your doctor will rely on the date of your last natural menstrual bleeding to predict when birth is due. However, it will not

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

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

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 there is a change in your health that you think may be due to Floret, inform your doctor.

An increased risk of blood clots in the veins (venous thromboembolism [VTE]) or blood clots in the arteries (arterial thromboembolism [ATE]) exists in all women using combined hormonal contraceptives. For further information on the different risks resulting from taking combined hormonal contraceptives, see section 2 "Before using the medicine".

immediately

Rare side effects (effects that appear in 1-10 out of 10,000 users):
• Harmful blood clots in a vein or artery, for

in a leg or foot (deep vein thrombosis) in a lung (pulmonary embolism) heart attack

blood clots in the liver, stomach/intestine, - blood clots in the liver, stomachimiestrie, kidneys or eyes

The risk of developing a blood clot may be higher if you have any other factor that increases it (for more information about the risk factors and symptoms of blood clots, see

Signs of a severe allergic reaction or worsening of hereditary angioedema:

- swelling of the hands, face, lips, mouth, tongue or throat. Swelling of the tongue or throat may lead to difficulty swallowing

or throat may lead to difficulty swalld and breathing
- A red bumpy rash (hives) and itching Signs of breast cancer include:
- dimpling of the skin
- changes in the nipple
- lumps you see or feel

pelvic pain pain during sex

Signs of severe liver problems include:

If any of the above-mentioned effects occurs, proceed immediately to the doctor. He may instruct you to stop taking **Floret**.

nausea

fluid retention

weight loss

• increased libido
• vaginal or breast discharges

Other reported side effects
• during the first months there may
be bleeding between your periods
(spotting or light bleeding). This bleeding
will usually stop once your body has
adjusted to the use of Floret. If the
bleeding is heavy, prolonged or starts
again, refer to the doctor (see in section
4 "Bleeding between the periods")
• chloasma (house.")

or UV radiation. or oviradiation:
occurrence or worsening of a
movement disorder called chorea.
ulcerative colitis
medical conditions that may worsen

during pregnancy or previous use of the medicine:

gallstones rare medical conditions such as systematic lupus erythematosus blister-like rash (herpes gestationis) during

blister-like rash (herpes gestations) during pregnancy inherited deafness of the otosclerosis type Crohn's disease if you or someone in your family suffer from

• continues for more than a few months. • started after you have been taking **Floret** for a while ntinues even after you have stopped taking

What the medicine looks like and what the package contains:
Round, biconvex, yellow tablets. The tablets come in blisters of 21 tablets. Each package contains 1, 3 or 4 blisters. Not all package sizes may be marketed.

Manufacturer and registration holder:

If you started a new package late, or you extended the break beyond 7 days, you may not be protected from pregnancy. If you had sex during the last 7 days, consult the doctor. You may need emergency contraception. Additionally, use a contraceptive method such as a condom for the next 7 days. If you lost a tablet If you lost a tablet
Act according to one of the 2 following options:
Take the last tablet of the package in place of
the lost tablet. Continue taking the rest of the
tablets on their proper days. Your menstrual
cycle will be one day shorter than normal,
but your contraceptive protection will not be
impaired. After the 7-day break, your starting
day will change, and will be one day earlier
than the previous nackage.

oay will charge, and will be one day earlier than the previous package.

Or, if you have another package and you do not want to change the starting day of your menstrual cycle, take a tablet from the other package. Continue taking all the other tablets from your current package as usual. You can then keep the opened package as a spare one, in case you lose any more tablets.

If you safer in voliding to identified on more than 12 hours after taking the tablet, follow the instructions in section "If you forgot to take the medicine". Tell the doctor if the stomach upset persists or gets worse. He may recommend using an extrementary

When you are interested in becoming

2 "Before using the medicine". Severe side effects - refer to the doctor

section 2).

vaginal discharge that smells and/or contains blood unusual vaginal bleeding

severe pain in the upper abdomen yellowing of whites of the eyes (jaundice) viral liver inflammation (hepatitis) itching all over the body

Additional side effects, less severe Common side effects (effects that appear in 1-10 out of 100 users):

 weight gain
 headache
 mood swings or depressive mood
 pain or tenderness of the breasts Uncommon side effects (effects that appear in 1-10 out of 1,000 users)

• vomiting and indigestion

migraine
 decreased libido
 breast enlargement
 rash, which may be itchy

Rare side effects (effects that appear in 1-10 out of 10,000 users)
• intolerance to contact lenses

again, feel of the occol (see in section 4 "Bleeding between the periods") chloasma (brown-yellow patches on the skin). These patches may appear even after using Floret for several months. The incidence of chloasma can be reduced by avoiding sunlight or IIV radiation.

yellowing of the skin (jaundice) persistent itching (pruritus) liver or kidney function problems

If a side effect appears, 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.

leaflet, consult the doctor.

Bleeding between the periods
Some women who take Floret have light
bleeding or spotting between periods,
especially during the first few months of
treatment. Normally, this bleeding will stop
within a day or two and is nothing to worry
about. Keep taking Floret as usual. The effect
will most likely disappear after using a few
packages.
Bleeding between the periods can also occur
due to irregular use of Floret, therefore, be
sure to take the pill at the same time every
day. Also, bleeding between the periods can
be due to use of other medicines.
Consult the doctor if you get bleeding between
the periods or spotting that:
• continues for more than a few months.

Side effects can be reported to the Ministry of Health via the link "דיווח על תופעות לוואי עקב טיפול תרופתי" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting, or via the following link: https://sideeffects.health.gov.il

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).

Dexcel® Ltd.

1 Dexcel St., Or Akiva 3060000, Israel

6. Additional information In addition to the active ingredients, this medicine also contains:

Drug registration number at the national drug registry of the Ministry of Health: 140.57.31528.00

Floret PIL PB1120-11

cause you or your baby any harm if you become pregnant straight away.

need them.
If you have further questions on the use of this medicine, consult the doctor or pharmacist.

stroke minor stroke or temporary stroke-like symptoms known as a transient ischemic attack (TIA)

Signs of a blood clot (see in section 2 "blood clots")

Signs of cervical cancer include:

abdominal pain

in you of someone in your family suffer from sickle cell anemia swelling of body parts (hereditary angioedema) hereditary disease called poryphyria cervical cancer

https://sideeffects.health.gov.il

5. How to store the medicine

• Avoid poisoning! This medicine, and any other medicine, should 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 (תובים אראר) 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

Revised in July 2020.