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

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

FEMINET®- Tablets

Each tablet contains: Desogestrel 0.15 mg and Ethinylestradiol 0.02 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".

Important things to know about combined hormonal contraceptives (CHCs):
- They are one of the most reliable reversible methods of contraception if used correctly.
- They slightly increase the risk of blood clots in the veins and arteries, especially in the first year of treatment or when restarting treatment with CHCs after a break of 4 or more weeks.
- Please be alert and refer to your doctor if you think you have symptoms of a blood clot (see section 4, "Side Effects").
- Some women should not take the pill due to current medical problems or illnesses. Please read this leaflet to make sure **Feminet** is right for you.
- To prevent pregnancy, it is important to take **Feminet** as instructed and start each pack on time. Please make sure you understand what to do if you miss a pill or if you think you are pregnant.

Read this entire leaflet carefully before using this medicine since it contains important information for you.
- 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 to yours.

1. What is the medicine intended for?

Feminet is a combined oral contraceptive pill ("the Pill"). This low-dose contraceptive contains two types of female sex hormones, estrogen and progestogen. These hormones prevent the release of an egg from your ovaries so you can't get pregnant. **Feminet** also thickens the cervical fluid (mucus), which makes it more difficult for the sperm to enter the womb.
Therapeutic group: combined estrogen-progestogen contraceptive.
Feminet will not protect you from sexually transmitted infections, such as Chlamydia or HIV (AIDS). Only condoms can help to do that.
Take Feminet according to instructions to prevent pregnancy.

2. Before using the medicine

General notes

Before you start using **Feminet** you should read the information on blood clots in section 2. It is particularly important to read what the symptoms of a blood clot are - see section 4 "Side effects". It's important that you understand the benefits and risks of taking the Pill before you start taking it, or when you decide if to continue taking it. Although the Pill is suitable for most healthy women, it is not suitable for everyone.
Tell your doctor if you have any of the illnesses or risk factors mentioned in this leaflet.
Before you start taking the Pill
- Your doctor will ask you about yours and your family's medical problems and check your blood pressure. You may also need other checks, such as a breast examination.

While you are taking the Pill
- You will need **regular check-ups** with your doctor, mostly when you need another prescription for the Pill.

- You will need to go to **regular cervical smear tests.**
- **Check your breasts** and nipples every month to detect changes - tell your doctor if you see or feel anything odd, such as lumps or dimples of the skin.
- **If you need a blood test**, tell your doctor you are taking the Pill since the Pill may affect the results of some tests.
- **If you are going to have an operation**, make sure your doctor knows about it. You may need to stop taking the Pill about 4-6 weeks before the operation. This is to reduce your risk of a blood clot (see in section 2, "**When you should not use Feminet**"). Your doctor will tell you when you can start taking the Pill again.

When you should not use Feminet
Do not use **Feminet** if you have any of the conditions listed below. Your doctor will discuss with you about another contraception that will be more suitable. See also in section 2, "**Special warnings regarding the use of the medicine**".

Do not use the medicine if:
- You have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), in your lungs (pulmonary embolism, PE), or in other organs;
- You know you have a disorder affecting your blood clotting - for example, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor 5 Leiden or antiphospholipid antibodies;
- You need an operation or if you cannot stand on your feet for a long time (see in section 2 "**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 which may increase your risk of a blood clot in the arteries:
  - Severe diabetes with blood vessel damage
  - Very high blood pressure
  - Very high blood lipid level (cholesterol or triglycerides)
  - A condition known as hyperhomocysteinemia
- You have (or have ever had) a type of migraine called "migraine with aura";
- You have or have had a **severe liver disease**;
- You have ever had a **liver tumor**;
- You have or have had a **pancreatitis** (an inflammation of the pancreas) associated with high levels of fatty substances in your blood;
- You have cancer affected by sex hormones, such as some **cancers of the breast**, **womb lining or ovary;**
- You have **vaginal bleeding** that has not been explained by your doctor;
- You have abnormal growth of the womb lining (Endometrial hyperplasia);
- You are **hypersensitive (allergic)** to the active ingredients or to any of the other ingredients this medicine contains (see section 6);
- You have hepatitis C and you are taking medicinal products containing ombitasvir/ paritaprevir/ ritonavir and dasabuvir or glecaprevir/ pibrentasvir (see section "Drug interactions");
- You are pregnant or you suspect you may be pregnant (see section "Pregnancy, breastfeeding and fertility").

If you suffer from any of these, or if one of them appears for the first time while taking **Feminet**, contact your doctor as soon as possible. Do not use **Feminet.**

Special warnings regarding the use of the medicine
When should you refer to your doctor?

Seek urgent medical attention
- If you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lungs (i.e. pulmonary embolism), heart attack or stroke (see description of the symptoms in section 4 "Side effects").
- If you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives, potentially with difficulty breathing (see the below section "Before using **Feminet**, tell your doctor if any of the following conditions apply to you").

Before using Feminet, tell your doctor if any of the following conditions applies to you;
If the condition develops or gets worse while you are using **Feminet, you should also tell your doctor:**
- You have ever had **heart, circulation or blood clotting problems**
- You have **diabetes**
- You have ever had **kidney or liver problems**
- You have ever had **severe depression**
- You have ever had **migraines**
- You have had **problems during pregnancy or while using the Pill**, such as: itching of the whole body, jaundice which was not caused by infection, gallstones, systemic lupus erythematosus (SLE), a blister-like rash (herpes gestationis), a hearing problem (otosclerosis); other rare conditions called porphyria, hereditary and acquired angioedema (you should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives, potentially with difficulty breathing. Products containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema).
- You have **brown patches on your face or body** (chloasma). If so, avoid too much exposure to the sun or ultraviolet light.
- You have Crohn's disease or ulcerative colitis.
- You have systemic lupus erythematosus.
- You have hemolytic uremic syndrome (a blood clotting disorder causing kidney failure).
- You have sickle cell anemia (an inherited disease of the red blood cells).
- You have elevated blood lipid levels (hypertriglyceridemia) or a positive family history of this condition. Hypertriglyceridemia has been associated with an increased risk of developing pancreatitis.
- You need an operation or you cannot stand on your feet for a long time (see in section 2 "Blood clots").
- You have just given birth, you are at increased risk of blood clots. You should ask your doctor how soon after delivery you can start using **Feminet** (see section "The Pill and thrombosis").
- You have an inflammation in the veins under the skin.
- You have varicose veins.

The Pill and thrombosis
Blood clots
Using a combined hormonal contraceptive, such as **Feminet**, increases your risk of developing a blood clot compared with not using one. In rare cases, a blood clot can block blood vessels and cause serious problems.
Blood clots can develop
- In veins (called "venous thrombosis" or VTE)
- In arteries (called "arterial thrombosis" or ATE)

Recovery from blood clots is not always complete. Rarely, there may be severe lasting effects or, very rarely, they may be fatal.
It is important to remember that the overall risk of a harmful blood clot due to Feminet is small.

How to recognize a blood clot
The signs of blood clots are listed in section 4 "Side effects". If you notice any of the signs of a blood clot, seek urgent medical treatment.
Blood clots in a vein
What can happen if a blood clot forms in a vein?
- The use of CHCs has been connected with an increased risk of blood clots in veins. However, these side effects are rare.
- 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 lodges in the lung, it can cause a pulmonary embolism.
- Very rarely, a clot may form in a vein in another organ such as the eye.

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 CHC for the first time. The risk may also be higher if you restart taking a CHC (the same or a different product) after a break of 4 weeks or more.
After the first year the risk gets smaller, but is always slightly higher than if you were not using a CHC.
When you stop taking **Feminet**, your risk of a blood clot returns to normal within a few weeks.

What is the risk of developing a blood clot?
The risk depends on your natural risk of developing venous thromboembolism and on the type of CHC you are taking.
The overall risk of developing a blood clot in the leg or lungs with **Feminet** is small.
- Out of 10,000 women who are not using any CHC and are not pregnant, about 2 will develop a blood clot in a year.
- Out of 10,000 women who are using a CHC 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 CHC that contains desogestrel, such as **Feminet**, about 9-12 women will develop a blood clot in a year.
- The risk of a blood clot will vary according to your personal medical history (see "**Factors that increase your risk of a blood clot**" below).

Factors that increase your risk of a blood clot in a vein
The risk of a blood clot with **Feminet** is small, but some conditions will increase the risk. Your risk is higher:
- If you are very overweight (BMI over 30 kg/m^2);
- 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 this case, you may have a hereditary blood clotting disorder;
- If you need to have an operation, or if you cannot stand on your legs for a long time due to an injury or illness, or if your leg is in a cast. The use of **Feminet** may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop taking **Feminet**, ask your doctor when you can start using it again;
- As you get older (particularly above 35 years);
- If you gave birth less than a few weeks ago.

The risk of developing a blood clot increases the more conditions you have.
Air travel (above 4 hours) may temporarily increase your risk of a blood clot, especially if you have some of the other factors listed.
It is important to tell the doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that you should stop using **Feminet**.
If one of the conditions above changes while using **Feminet**, for example if a family member experiences a thrombosis for an unknown reason, or if you gain a lot of weight, tell your 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 clot in the artery may cause severe problems. For example, it may cause a heart attack or 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 due to the use of **Feminet** is very small, but may increase:
- With increasing age (above 35 years);
- **If you smoke.** When using a CHC like **Feminet**, it is recommended to stop smoking. If you are unable to stop smoking and are older than 35, your doctor may advise you to use a different type of contraceptive;
- If you are overweight;
- If you have high blood pressure;
- If a member of your immediate family has had a heart attack or stroke at a young age (below the age of 50). In this case, you may also have a higher risk of having a heart attack or a stroke;
- If you, or someone in your immediate family, have high blood lipid levels (cholesterol or triglycerides);
- If you get migraines, especially migraines with aura;
- If you have a heart problem (a heart valve disorder, a rhythm disturbance called atrial fibrillation);
- If you have diabetes.

If you have more than one of these conditions or if any of them are particularly severe, the risk of developing a blood clot may be increased even more.
If any of the conditions listed above changes while using **Feminet**, for example, if you start smoking, a family member experiences a thrombosis for an unknown reason or if you gain a lot of weight, tell your doctor.

The Pill and cancer
The Pill reduces the risk of ovarian and uterine cancer, if taken for a prolonged period. However, it also seems to slightly increase the risk of **cervical cancer**, although this may be due to having sex without a condom rather than the Pill itself. All women should have regular **smear tests**.

If you have **breast cancer**, or have had it in the past, do not use the Pill. The Pill slightly increases your risk of breast cancer. The risk increases the longer you use the Pill, but it returns to normal within about 10 years of stopping the Pill. Since breast cancer is rare in women under 40 years of age, the extra number of breast cancer cases in current or recent users of the Pill, is small. For example:
- Out of 10,000 women **who have never taken the Pill**, about 16 will develop breast cancer by the age of 35.
- Out of 10,000 women **who took the Pill for 5 years in their early twenties**, about **17-18** women will develop breast cancer by the age of 35.
- Out of 10,000 women **who have never taken the Pill**, about **100** will develop breast cancer by the age of 45.
- Out of 10,000 women **who took the Pill for 5 years in their early thirties**, about **110** will develop breast cancer by the age of 45.

Your risk of breast cancer is higher if you have:
- A family member (mother, sister or grandmother) who has had breast cancer in the past.
- Severe obesity.

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

Taking the Pill has also been linked to liver diseases, such as jaundice and non-cancer liver tumors, but this is rare. Very rarely, the Pill has also been linked with some forms of liver cancer in women who have taken it for a long time.
Refer to the doctor immediately if you get a severe pain in your stomach, or yellow skin or eyes (jaundice). You may need to stop taking **Feminet**.

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

Drug interactions
If you are taking or have recently taken other medicines, including non-prescription medicines, herbal products and nutritional supplements, tell the doctor or pharmacist. Also, tell any doctor or dentist who prescribes you another medicine (or a pharmacist) that you are taking **Feminet**. This is because **Feminet** can also affect how well other medicines work, causing either an increase in effect (e.g., ciclosporin) or a decrease in effect (e.g., lamotrigine). Remind your doctor if you are taking these in case your treatment needs to be adjusted.
Also, check the leaflets that come with all of your medicines to see if they can be taken with hormonal contraceptives.

Some medicines may stop Feminet from working properly. These include medicines used for the treatment of:
- **Epilepsy** (primidone, phenytoin, phenobarbital, carbamazepine, oxcarbazepine, topiramate, felbamate, modafinil);
- **Tuberculosis** (rifampicin);
- **HIV infections** (ritonavir, nelfinavir, nevirapine, efavirenz);
- **Hepatitis C virus infection** (e.g., boceprevir, telaprevir);
- Other **infectious diseases** (e.g., griseofulvin);
- **High blood pressure in blood vessels of the lungs** (bosentan);
- **Depressive moods** (medicine or preparations containing hypericum - St. John's Wort);

If you are taking medicines or herbal products that might make **Feminet** less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on **Feminet** may last up to 28 days after stopping the medicine, it is necessary to use the barrier contraceptive method for that long.

Do not use **Feminet** if you have hepatitis C and you are taking medicinal products 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 type of contraceptive prior to start of the treatment starting with these medicinal products.
Feminet can be restarted approximately 2 weeks after completion of this treatment. See section "Do not use this medicine if".

Tests and follow-up
If you need to do a blood test, tell your doctor that you are using **Feminet** since the Pill can affect the results of certain blood tests.

Use of the medicine and food
There are no special instructions regarding food or drink while taking **Feminet**.

Pregnancy, breastfeeding and fertility
Do not use **Feminet** if you are pregnant. If you think you might be pregnant, do a pregnancy test to confirm you are pregnant before you stop taking **Feminet**.
Feminet is not recommended for use while breastfeeding. Ask your doctor about alternative contraception. Breastfeeding may not stop you getting pregnant.

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

Important information about some of the ingredients of the medicine
This medicine contains lactose. If you have been told by the doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Use in adolescents
No clinical data on efficacy and safety are available in adolescents below 18 years.

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.
How to take Feminet
To prevent pregnancy, always take **Feminet** exactly as described in this leaflet or according to the instructions of your doctor or pharmacist.
Take Feminet every day for 21 days.
Feminet comes in a blister of 21 pills, each marked in the blister with the day of the week.
- Take your pill every day at the same time.
- Start by taking the tablet marked with the correct day of the week.
- Follow the direction of the arrows on the blister. Take one pill every day, until you finish all 21 pills.
- Swallow the pill whole, with water if necessary.
- Do not crush/halve/chew the pill as these actions may interrupt the absorption of the active substance of the pill and thus impair its efficacy.

Then take a 7-day pill-free break.
After you have taken all 21 pills in the blister, you have 7 days when you do not take pills. So, if you took the last pill of one pack on a Friday, take the first pill of the next pack on the Saturday of the following week.
Within a few days of taking the last pill from the blister, menstrual-like bleeding is supposed to appear. The bleeding may not be finished by the time you have to start the next blister of pills.
You do not need additional contraception during the 7 days without the pill, as long as you have taken the pills properly and start the next blister of pills on time.
Afterwards start the next blister
Start taking the next **Feminet** blister after the 7 pill-free days, whether the bleeding has stopped or not. Always start the new blister on time.

As long as you take **Feminet** correctly, you will always start the new blister on the same day of the week.

Starting Feminet
As a new user or when you start taking the Pill again after a break
Either take the first **Feminet** pill on the first day of your next period. By starting this way, you will have contraceptive protection from the first pill.
Or, if your period has already started, start taking **Feminet** on the fifth day (counting the first day of your period as day 1), whether your bleeding has stopped or not. You must also use extra contraception, such as condoms, until you have taken the first 7 pills correctly.

Changing to Feminet from another contraceptive pill
- **If you are currently on a 21-day Pill:** Start taking **Feminet** the next day after you finish the previous blister. You will have contraceptive protection from the first pill, but the bleeding will appear only after you finish the first **Feminet** blister.
- **If you are currently on a 28-day Pill:** Start taking **Feminet** a day after taking the last active pill. You will have contraceptive protection from the first pill. The bleeding will not appear until you finish the first **Feminet** blister.
- **Or if you are taking a progestogen-only pill ("mini-pill" or POP):** Start **Feminet** on the first day of bleeding, even if you have already taken the mini-pill of that day. You will have immediate contraceptive protection. If you don't usually have bleeding while taking the progestogen-only pill, you can stop taking it at any day and start taking **Feminet** the next day. You will need to use extra contraception, such as a condom, for 7 days.

Changing to Feminet from a progestogen-only injection, implant or progestogen releasing intrauterine device (IUD)
Start taking **Feminet** when your next injection is due or on the day that your implant or IUD is removed. Make sure to use an additional contraceptive method, such as a condom, for the first 7 days that you take **Feminet**.
Starting Feminet after a miscarriage or abortion
If you have had a miscarriage or an abortion, your doctor may instruct you to start taking **Feminet** immediately. In this case you will have contraceptive protection from the first pill.
Contraception after childbirth
If you have just given birth, consult your doctor regarding contraception.
If you are not breastfeeding:
- You can start taking **Feminet** 3 weeks after birth, or,
- You can start taking **Feminet** more than 3 weeks after birth, but you need to use extra contraception, such as a condom, until you have taken the first seven pills correctly.
- If you have had sex since the birth, there is a chance that you might be pregnant, therefore you should use another form of contraception such as a condom. In this case, take the first **Feminet** pill on the first day of your next period.

A missed pill
If the delay in taking one pill is less than 12 hours:
- Take the missed pill immediately and the rest of the pills as usual. This may mean taking two pills in one day.
- Don't worry, your contraceptive protection should not be reduced.

If the delay in taking one pill is more than 12 hours, or if you missed more than one pill:
- Take the last pill you forgot immediately.
- Leave previously missed pills in the blister.
- Take the next pills as usual. This may mean taking two pills in one day.
- Use additional contraception (condoms for example) during the next 7 days.
- Check how many pills are left in the pack after the last missed pill:

If there are less than 7 pills left in the pack:
- Don't forget to use additional contraception during the next 7 days.
- When you finish the pills blister, start a new blister the next day, without a break.
- If you do not get your period after finishing the second package, do a pregnancy test before starting another blister.
- **If you have missed one or more pills during the first week (days 1 to 7) and you had sex during that week, you may become pregnant.** Contact your doctor or pharmacist for advice as soon as possible.

If there are 7 pills or more left in the pack:
- Don't forget to use additional contraception during the next 7 days.
- When you finish the pack, keep the 7-day break before starting a new pack.
- **If you have missed one or more pills during the first week (days 1 to 7) and you had sex during that week, you may become pregnant.** Contact your doctor or pharmacist for advice as soon as possible. They may recommend you use emergency contraception.

If you have missed any of the pills in the blister, and you do not get your period during the first pill-free break, you may be pregnant. Contact your doctor, or do a pregnancy test yourself.

If you start a new blister of pills late, or you make your "week off" longer than 7 days, you may not be protected from pregnancy. If you had sex in the last 7 days, consult your doctor or pharmacist. You may need to consider emergency contraception. Also, use extra contraception, such as a condom, for 7 days.

A lost pill
If you lost a pill,
Either take the last pill of the blister instead of the lost pill. Then take the rest of the pills on their proper days. Your menstrual cycle will be one day shorter than usual, but your contraceptive protection won't be affected. After the 7 pill-free days, you will have a new starting day, one day earlier than before.
Or, if you do not want to change the first day of taking the pill, take a pill from another blister. Then, take the rest of the pills from your current blister, as usual.
You can then keep the additional open blister as a spare one, in case you lose any more pills.

If you are sick or have diarrhea
If you are sick (*vomit*) or suffer from severe diarrhea, your body will not receive the usual dose of hormones from this pill.
If you vomit within **3-4 hours** of taking the Pill, it is similar to a missed pill. Follow the instructions about missed pills. See in section 3 **"A missed pill"**.
If you have severe diarrhea for **more than 12 hours after taking Feminet**, follow the instructions of being more than 12 hours late. See in section 3, **"A missed pill"**.
Talk to your doctor if your indigestion continues or worsens. He may recommend another form of contraception.

Missed period - could you be pregnant?
Occasionally, you may miss a bleeding during the pill-free week break. This could indicate that you are pregnant, but it is very unlikely if you have taken the pills correctly. Start the next blister at the usual time. If you think you may have put yourself at risk of pregnancy (for example, by missing pills or taking other medicines), or if a second bleeding does not appear, you should do a pregnancy test. If you are pregnant, stop taking **Feminet** and refer to your doctor.

Taking more than one pill should not cause harm
It is unlikely that taking more than one pill will cause any harm, but you may feel nausea, vomit or have some vaginal bleeding. Talk to your doctor if you have any of these symptoms.
If a child has accidently swallowed the pill, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

You can delay the period
If you want to delay having a period, finish the blister of pills you are taking. Start the next blister on the next day, without a break. Take this blister the usual way. After the second blister, leave 7 pill-free days as usual, then start the next blister, as usual. While using the second blister, you may have unexpected bleedings or spotting on the days of taking the pill, but don't worry.

When you want to get pregnant
If you are planning a baby, it's best to use another method of contraception after stopping **Feminet**, until you have a proper period. Your doctor relies on the date of your last natural period before you get pregnant, to predict when birth is due. However, it will not cause you or your baby any harm if you get pregnant straight away.

4. Side effects

Like any medicine, the use of **Feminet** 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 get any side effect, especially if severe and persistent, or have any change to your health that you think may be due to **Feminet**, please talk to your doctor.
An increased risk of blood clots in the veins or the arteries exists in all women using CHCs. See section 2 "**Before using the medicine**".

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

Severe side effects - refer to the doctor immediately:

Signs of deep vein thrombosis include:
Swelling of one leg or along a vein in the leg or foot, especially when accompanied by:
- Pain or tenderness in the leg which may be felt only when standing or walking;
- Increased warmth in the affected leg;
- Change in color of the skin on the leg e.g., turning pale, red or blue.

Signs of pulmonary embolism:
- Sudden unexplained shortness of breath or rapid breathing;
- Sudden cough without an obvious cause, which may bring up blood;
- Sharp chest pain which may increase with deep breathing;
- Severe light-headedness or dizziness;
- Rapid or irregular heartbeat;
- Severe stomach pain;

If you are unsure, refer to the doctor as some of these symptoms, such as coughing or shortness of breath, may be mistaken for a milder condition such as a respiratory tract infection (e.g., a "common cold").

Signs of retinal vein thrombosis (blood clot in the eye):
Symptoms that mostly occur in one eye: immediate loss of vision or painless blurring of vision which can progress to loss of vision.

Signs of a heart attack:
- Chest pain, discomfort, pressure or heaviness;
- Sensation of squeezing or fullness in the chest, arm or below the breastbone;
- Fullness, indigestion or choking feeling;
- Upper body discomfort radiating to the back, jaw, throat, arm and stomach;
- Sweating, nausea, vomiting or dizziness;
- Extreme weakness, anxiety or shortness of breath;
- Rapid or irregular heartbeat.

Signs of a stroke:
- 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 coordination;
- Sudden, severe or prolonged headache with no known cause;
- Loss of consciousness or fainting with or without seizures.

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.

Signs of blood clots blocking other blood vessels:
- Swelling and slight blue discoloration of an extremity;
- Severe stomach pain (acute abdomen).

Signs of severe allergic reaction to Feminet: Swelling of the face, lips, mouth, tongue or throat.

Signs of breast cancer include:
- Dimpling of the skin;
- Changes in the nipple;
- Any lump you can see or feel.

Signs of cervical cancer include:
- Vaginal discharge with an unpleasant smell and containing blood;
- Unusual vaginal bleeding;
- Pelvic pain;
- Painful sex.

Signs of severe liver problems include:
- Severe pain in the upper abdomen;
- Yellowing of the skin and eyes (jaundice).

If you think you may have any of these, refer to a doctor immediately. You may need to stop taking **Feminet**.

Additional side effects
Common side effects (effects that occur in 1-10 out of 100 users)
- **Headache;**
- **Weight gain;**
- **Breast problems,** such as painful or tender breasts;
- **Depression or mood changes;**
- **Stomach problems,** such as nausea, abdominal pain;

Uncommon side effects (effects that occur in 1-10 out of 1,000 users)
- **Breast enlargement;**
- **Vomiting;**
- **Diarrhea;**
- **Fluid retention** (swollen hands, ankles or feet – a sign of fluid retention);
- **Decreased sexual desire;**
- **Migraine** (refer to a doctor as soon as possible if this is your first migraine or it's worse than usual, or if the headache is severe, unusual or long lasting);
- **Skin problems, such as rash or hives;**

Rare side effects (effects that occur in 1-10 out of 10,000 users)
- **Changes in vaginal secretions – irregular vaginal bleeding** - see in section 4 "Breakthrough bleeding should not last long";
- **Breasts producing a milky fluid from the nipples;**
- **Hypersensitivity reaction;**
- **Discomfort of the eyes if you wear contact lenses;**
- **Erythema nodosum (bruise-like swelling to the shins);**
- **Erythema multiforme (this is a skin condition);**
- **Decreased weight;**
- **Increased sexual desire;**
- **Harmful blood clots** in a vein or artery, for example:
  - in the leg or foot;
  - in the lung;
  - heart attack;
  - stroke;
  - mini stroke or temporary stroke-like symptoms, known as temporary ischemic attack;
  - blood clots in the liver, abdomen/ intestine, kidneys or eye.
  The risk of having a blood clot may be higher if you have any other conditions that increase this risk (see section 2).
- Severe **allergic reaction** to **Feminet**
- **Breast cancer**
- **Cervical cancer**
- Severe **liver problems**
- **Hypertension**
- **Gallstones**
- **Chorea** (a problem in the nervous system which causes sudden uncontrolled movements (spasms))
- Worsening of **systemic lupus erythematosus**
- **Stomach and intestine problems** such as pancreatitis, Crohn's disease; ulcerative colitis
- Worsening of **otosclerosis** (a hearing problem)
- **Blood sugar problems**
- Worsening of a rare condition called **porphyria**
- Worsening of **skin problems**, such as brown spots on the face and body (chloasma), a blister-like rash (herpes gestationis)

Side effects with unknown frequency (effects for which a frequency has not yet been determined):
- Angioedema, particularly in patients who already have a (family) history of angioedema.

Tell your doctor or pharmacist, if you are worried about any of the side effects which you think may be caused by **Feminet.** Also, tell them if existing conditions worsen while taking **Feminet**.

Bleeding between periods should not last long
A few women have little, unexpected bleeding or spotting while taking **Feminet**, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking **Feminet** as usual; the problem should disappear after the first few blisters.

You may also have unexpected bleeding if you are not taking the pills regularly, so try to take the Pill at the same time every day. Also, unexpected bleeding can sometimes be caused by other medicines.
Make an appointment with your doctor if you have breakthrough bleeding or spotting that:
- continues for longer than the first few months of use
- starts after you've been taking **Feminet** for a while
- continues even after you've stopped taking **Feminet**.

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 below 25°C, in the original package.
- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, **Feminet** also contains:
Lactose monohydrate, potato starch, povidone, silica colloidal anhydrous, stearic acid, hypromellose, macrogol 6000, alpha-tocopherol, magnesium stearate, propylene glycol, quinoline yellow (E104).
What the medicine looks like and what the package contains:
Round, convex, light-yellow colored tablets with an imprint "RG" on one side and "P9" on the other side.
Every package of **Feminet** contains 1, 3 or 4 blisters of 21 tablets. Not all package sizes may be marketed.

Revised in July 2022 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:
128-57-30568-00

Feminet PIL PB0922-08

Manufacturer and registration holder:
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