Package leaflet: Information for the user

Femilux 3 mg/0,02 mg filmomhulde tabletten

drospirenone and ethinylestradiol

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

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

1. What Femilux is and what it is used for

- This medicine is a contraceptive pill and is used to prevent pregnancy.
- Each of the 24 pink tablets contain a small amount of two different female hormones, namely drospirenone and ethinylestradiol.
- The 4 white tablets contain no active substances and are also called placebo tablets.
- Contraceptive pills that contain two hormones are called “combination” pills.

2. What you need to know before you take Femilux

General notes

Before you start using Femilux you should read the information on blood clots in section 2. It is particularly important to read the symptoms of a blood clot – see section 2 “Blood clots”.

Before you can begin taking this medicine, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure and, depending upon your personal situation, may also carry out some other tests.

In this leaflet, several situations are described where you should stop using this medicine, or where the reliability of this medicine may be decreased. In such situations you should either not have sex or you should take extra non-hormonal contraceptive precautions, for example, use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable as this medicine alters the monthly changes of body temperature and of the cervical mucus.

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

Do not take Femilux

You should not use Femilux if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor. Your doctor will discuss with you what other form of birth control would be more appropriate.

- if you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs
- if you know you have a disorder affecting your blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies
- if you need an operation or if you are off your feet for a long time (see section 'Blood clots')
- if you have ever had a heart attack or stroke
- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA – temporary stroke symptoms)
- if you have any of the following diseases that may increase your risk of a clot in the arteries:
  - severe diabetes with blood vessel damage
  - very high blood pressure
  - a very high level of fat in the blood (cholesterol or triglycerides)
  - a condition known as hyperhomocysteinaemia
- if you have (or have ever had) a type of migraine called 'migraine with aura'
- if you have (or have ever had) liver disease and your liver function is still not normal
- if your kidneys are not working well (renal failure)
- if you have (or have ever had) a tumour in the liver
- if you have (or have ever had) or if you are suspected of having breast cancer or cancer of the genital organs
- if you have any unexplained bleeding from the vagina
- if you are allergic to drospirenone, or ethinylestradiol, or any of the other ingredients of this medicine (listed in section 6). This may cause itching, rash or swelling
- if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see also in section "Other medicines and Femilux").

Warnings and precautions

Talk to your doctor or pharmacist before taking Femilux.

When should you contact 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 lung (i.e. pulmonary embolism), a heart attack or a stroke [see 'Blood clot' (thrombosis) section below].

For a description of the symptoms of these serious side effects please go to "How to recognise a blood clot".

Tell your doctor if any of the following conditions apply to you.
In some situations you need to take special care while using this medicine or any other combination pill, and your doctor may need to examine you regularly.
If any of the following conditions applies to you, you must inform your doctor before starting to use this medicine. If the condition develops, or gets worse while you are using Femilux, you should also tell your doctor.

- if a close relative has or has ever had breast cancer
- if you have a disease of the liver or the gallbladder
- if you have diabetes
- if you have depression
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- if you have systemic lupus erythematosus (SLE –; a disease affecting your natural defence system)
- if you have haemolytic uremic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys)
- if you have sickle cell anaemia (an inherited disease of the red blood cells)
- if you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas)
- if you need an operation, or you are off your feet for a long time (see in section 2 'Blood clots')
- if you have just given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking Femilux
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis)
- if you have varicose veins
- if you have epilepsy (see "Other medicines and Femilux")
- if you have a disease that first appeared during pregnancy or earlier use of sex hormones [for example, hearing loss, a blood disease called porphyria, skin rash with blisters during pregnancy (gestational herpes), a nerve disease causing sudden movements of the body (Sydenham's chorea)]
- if you have or have ever had golden brown pigment patches (chloasma), so called "pregnancy patches", especially on the face. If this is the case, **avoid direct exposure** to sunlight or ultraviolet light.
- if you experience symptoms of angioedema such as swollen face, tongue and/or throat, and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Products containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema.

BLOOD CLOTS

Using a combined hormonal contraceptive such as Femilux increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block blood vessels and cause serious problems.
Blood clots can develop

- in veins (referred to as a 'venous thrombosis', 'venous thromboembolism' or VTE)
- in the arteries (referred to as an 'arterial thrombosis', 'arterial thromboembolism' or ATE).

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

HOW TO RECOGNISE A BLOOD CLOT
Seek urgent medical attention if you notice any of the following signs or symptoms.

Are you experiencing any of these signs?	**What are you possibly suffering from?**
• swelling of one leg or along a vein in the leg or foot especially when accompanied by: • pain or tenderness in the leg which may be felt only when standing or walking • increased warmth in the affected leg • change in colour of the skin on the leg e.g. turning pale, red or blue	Deep vein thrombosis
• sudden unexplained breathlessness or rapid breathing; • sudden cough without an obvious cause, which may bring up blood; • sharp chest pain which may increase with deep breathing; • severe light headedness or dizziness; • rapid or irregular heartbeat • severe pain in your stomach; If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a 'common cold').	Pulmonary embolism
Symptoms most commonly occur in one eye: • immediate loss of vision or • painless blurring of vision which can progress to loss of vision	Retinal vein thrombosis (blood clot in the eye)
• chest pain, discomfort, pressure, heaviness • sensation of squeezing or fullness in the chest, arm or below the breastbone;	Heart attack

• 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	
• sudden weakness or numbness of the face, arm or leg, especially on one side of the body; • sudden confusion, trouble speaking or understanding; • sudden trouble seeing in one or both eyes; • sudden trouble walking, dizziness, loss of balance or coordination; • sudden, severe or prolonged headache with no known cause; • loss of consciousness or fainting with or without seizure. Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.	Stroke
• swelling and slight blue discolouration of an extremity; • severe pain in your stomach (acute abdomen)	Blood clots blocking other blood vessels

BLOOD CLOTS IN A VEIN

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

- The use of combined hormonal contraceptives has been connected with an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare. Most frequently, they occur in the first year of use of a combined hormonal contraceptive.
- If a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung it can cause a pulmonary embolism.
- Very rarely a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

When is the risk of developing a blood clot in a vein highest?

The risk of developing a blood clot in a vein is highest during the first year of taking a combined hormonal contraceptive for the first time. The risk may also be higher if you restart taking a combined hormonal contraceptive (the same product or a different product) after a break of 4 weeks or more.

After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive.

When you stop Femilux your risk of a blood clot returns to normal within a few weeks.

What is the risk of developing a blood clot?

The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you are taking.
The overall risk of a blood clot in the leg or lung (DVT or PE) with Femilux is small.

– Out of 10,000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.
– Out of 10,000 women who are using a combined hormonal contraceptive that contains levonorgestrel, norethisterone, or norgestimate about 5-7 will develop a blood clot in a year.
– Out of 10,000 women who are using a combined hormonal contraceptive that contains drospirenone, such as Femilux, between about 9 and 12 women will develop a blood clot in a year.
– The risk of having a blood clot will vary according to your personal medical history (see "Factors that increase your risk of a blood clot" below).

	Risk of developing a blood clot in a year
Women who are not using a combined hormonal pill/patch/ring and are not pregnant	About 2 out of 10,000 women
Women using a combined hormonal contraceptive pill containing **levonorgestrel, norethisterone or norgestimate**	About 5-7 out of 10,000 women
Women using Femilux	About 9-12 out of 10,000 women

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

The risk of a blood clot with Femilux is small but some conditions will increase the risk.
Your risk is higher:

- if you are very overweight (body mass index or BMI over 30kg/m^2);
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50). In this case you could have a hereditary blood clotting disorder;
- if you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of Femilux may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Femilux ask your doctor when you can start using it again.
- as you get older (particularly above about 35 years);
- if you gave birth less than a few weeks ago

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

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

It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that Femilux needs to be stopped.

If any of the above conditions change while you are using Femilux, for example a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

BLOOD CLOTS IN AN ARTERY

What can happen if a blood clot forms in an artery?
Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

Factors that increase your risk of a blood clot in an artery
It is important to note that the risk of a heart attack or stroke from using Femilux is very small but can increase:

- with increasing age (beyond about 35 years);
- **if you smoke.** When using a combined hormonal contraceptive like Femilux you are advised to stop smoking. If you are unable to stop smoking and are older than 35 your doctor may advise you to use a different type of contraceptive;
- if you are overweight;
- if you have high blood pressure;
- if a member of your immediate family has had a heart attack or stroke at a young age (less than about 50). In this case you could also have a higher risk of having a heart attack or stroke;
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides);
- if you get migraines, especially migraines with aura;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation)
- if you have diabetes.

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

If any of the above conditions change while you are using Femilux, 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.

Femilux and cancer

Breast cancer has been observed slightly more often in women using combination pills, but it is not known whether this is caused by the treatment. For example it may be that more tumours are detected in women on combination pills because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the combination hormonal contraceptives. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

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

Psychiatric disorders

Some women using hormonal contraceptives including Femilux 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 contact your doctor for further medical advice as soon as possible.

Bleeding between periods

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

What you must do if no bleeding occurs during the placebo days

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

Other medicines and Femilux

Always tell your doctor which medicines or herbal products you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you use Femilux. They can tell you if you need to take additional contraceptives precautions (for example condoms) and if so, for how long.

Some medicines
- can have an influence on the blood levels of Femilux
- can make it **less effective in preventing pregnancy**
- can cause unexpected bleeding.

These include:
- medicines used for the treatment of
  - epilepsy (for example primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine)
  - tuberculosis (for example rifampicin)
  - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efavirenz)
  - fungal infections (griseofulvin, ketoconazole)
  - arthritis, arthrosis (etoricoxib)
  - high blood pressure in the blood vessels in the lungs (bosentan)
- the herbal remedy St. John's wort

Femilux may influence the effect of other medicines, e.g.
- medicines containing ciclosporin
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures)
- theophylline (used to treat breathing problems)
- tizanidine (used to treat muscle pain and/or muscle cramps).

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Femilux with food and drink
This medicine may be taken with or without food, if necessary with a small amount of water.

Laboratory tests
If you need a blood test, tell your doctor or the laboratory staff that you are taking the pill, because hormonal contraceptives can affect the results of some tests.

Pregnancy and breast-feeding

Pregnancy
If you are pregnant, you must not take this medicine. If you become pregnant while taking this medicine you must stop immediately and contact your doctor. If you want to become pregnant, you can stop taking this medicine at any time (see also "If you stop taking Femilux").
Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding
Use of this medicine is generally not advisable when a woman is breast-feeding. If you want to take the pill while you are breast-feeding you should contact your doctor.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
There is no information suggesting that use of this medicine affects driving or use of machines.

Femilux contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Femilux

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
Each blister contains 24 active pink tablets and 4 white placebo tablets.

The two differently coloured tablets of **Femilux** are arranged in order. A strip contains 28 tablets.

Take one tablet of Femilux every day, if necessary with a small amount of water. You may take the tablets with or without food, but you should take the tablets every day around the same time.

Do not confuse the tablets: take a pink tablet for the first 24 days and then a white tablet for the last 4 days. You must then start a new strip straight away (24 pink and then 4 white tablets). There is therefore no gap between two strips.

Because of the different composition of the tablets it is necessary to begin with the first tablet on the upper left and that you take the tablets every day. For the correct order, follow the direction of the arrows on the strip.

Preparation of the strip

To help you keep track, there are 7 stickers each with the 7 days of the week for each strip of Femilux. Choose the week sticker that starts with the day you begin taking the tablets.For example, if you start on a Wednesday, use the week sticker that starts with “WED”.

Stick the corresponding strip in the upper left hand corner of the pack, on the "Start" position. There is now a day indicated above every tablet and you can see whether you have taken a certain pill. The arrows show the order you are to take the pills.

During the 4 days when you are taking the white placebo tablets (the placebo days), bleeding should begin (so-called withdrawal bleeding). This usually starts on the 2nd or 3rd day after the last pink active tablet of this medicine. Once you have taken the last white tablet, you should start with the following strip, whether your bleeding has stopped or not. This means that you should start every strip on the same day of the week, and that the withdrawal bleed should occur on the same days each month.

If you use this medicine in this manner, you are protected against pregnancy also during the 4 days when you are taking a placebo tablet.

When can you start with the first strip?

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

- *Changing from a combined hormonal contraceptive, or combined contraceptive vaginal ring or patch*
  You can start this medicine preferably on the day after the last active tablet (the last tablet containing the active substances) of your previous pill, but at the latest on the day after the tablet-free days of your previous pill finish (or after the last placebo tablet of your previous pill). When changing from a combined contraceptive vaginal ring or patch, follow the advice of your doctor.

- *Changing from a progestogen-only-method (progestogen-only pill, injection, implant or a progestogen-releasing IUD)*
  You may switch any day from the progestogen-only pill (from an implant or an IUD on the day of its removal, from an injectable when the next injection would be due) but in all of these cases you must use extra protective measures (for example, a condom) for the first 7 days of tablet-taking.

- *After a miscarriage*
  Follow the advice of your doctor.

- *After having a baby*
  You can start this medicine between 21 and 28 days after having a baby. If you start later than day 28, you must use a so-called barrier method (for example, a condom) during the first 7 days of this medicine use.

If, after having a baby, you have had sex before starting this medicine (again), you must first be sure that you are not pregnant or you must wait until your next period.

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

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

If you take more Femilux than you should

There are no reports of serious harmful results of taking too many tablets of this medicine.
If you take several tablets at once then you may feel sick or vomit or bleed from the vagina. Even girls who have not yet started to menstruate but have accidentally taken this medicine may experience such bleeding.

If you have taken too many Femilux tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

If you forget to take Femilux

The last 4 tablets in the **4th row** of the strip are placebo tablets. If you forget to take one of these tablets, this will have no effect on the reliability of Femilux. Throw away the forgotten placebo tablet.

If you forget a pink, active tablet (tablets 1-24 of your blister-strip) you must do the following:

- If you are **less than 24 hours** late taking a tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and then take the following tablets again at the usual time.
- If you are **more than 24 hours** late taking a tablet, the protection against pregnancy may be reduced. The greater the number of tablets that you have forgotten, the greater is the risk of becoming pregnant.

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

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

- **One tablet forgotten between days 1 – 7 (first row)**

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

- **One tablet forgotten between days 8 – 14 (second row)**

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

- **One tablet forgotten between days 15 – 24 (third or fourth row)**

  You can choose between two possibilities:

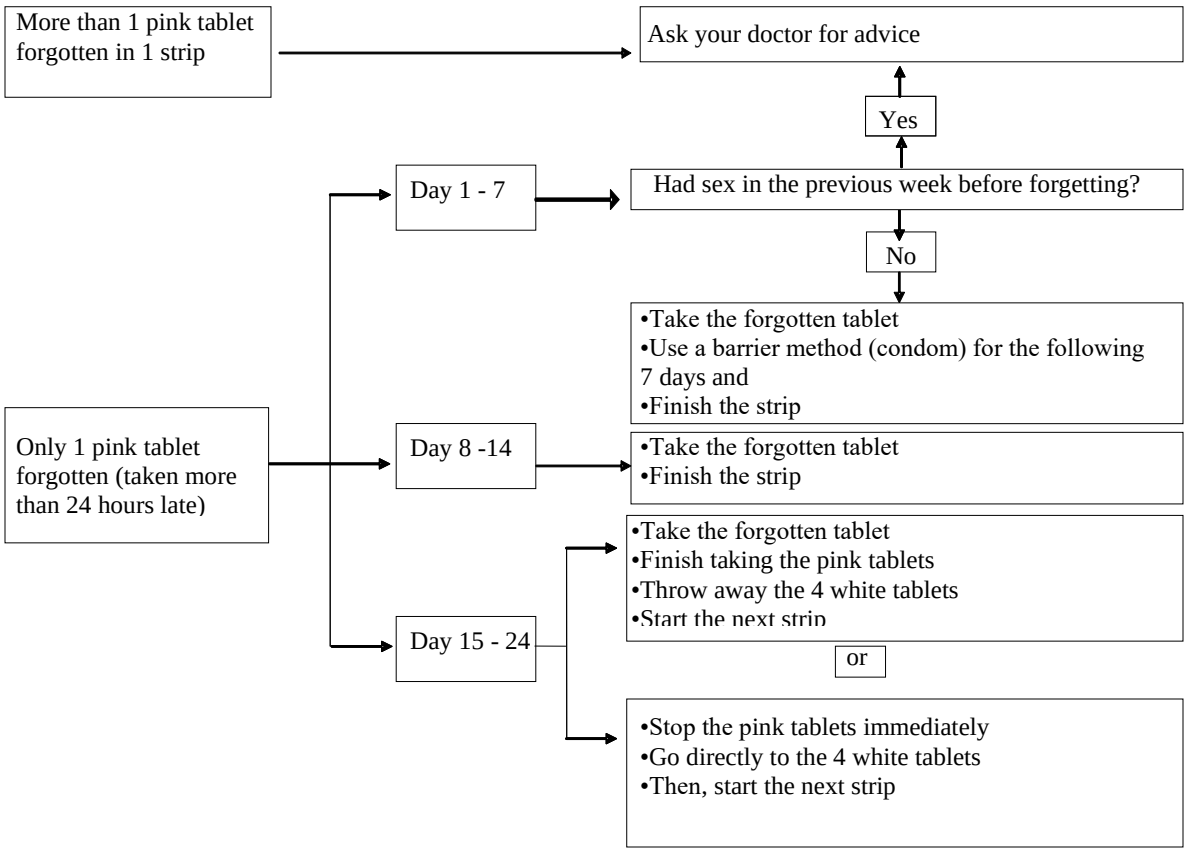
  1. Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. Instead of taking the white placebo tablets on this strip, throw them away, and start the next strip (the starting day will be different).

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

  2. You can also stop the active pink tablets and go directly to the 4 white placebo tablets **(before taking the placebo tablets, record the day on which you forgot your tablet)**. If you want to start a new strip on the day you always start, take the placebo tablets for *less than 4 days*.

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

- If you have forgotten any of the tablets in a strip, and you do not have a bleeding during the placebo days, this may mean that you are pregnant. You must contact your doctor before you start the next strip.



What to do in case of vomiting or severe diarrhoea

If you vomit within 3-4 hours of taking an active pink tablet or you have severe diarrhoea, there is a risk that the active substances in the pill will not be fully taken up by your body. The situation is almost the same as forgetting a tablet. After vomiting or diarrhoea, you must take another pink tablet from a reserve strip as soon as possible. If possible take it within 24 hours of when you normally take your pill. If this is not possible or 24 hours have passed, you should follow the advice given under "If you forget to take Femilux".

Delaying your period: what you need to know

Even if it is not recommended, you can delay your period by not taking the white placebo tablets from the 4th row and going straight to a new strip of this medicine and finish it. You may experience light or menstruation-like bleeding while using this second strip. Finish this second strip by taking the 4 white tablets from the 4th row. Then start your next strip.

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

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

If you take the tablets according to the instructions, then your period will begin during the placebo days. If you have to change this day, reduce the number of placebo days – when you take the white placebo tablets - (but never increase them – 4 is the maximum!). For example, if you start taking the placebo tablets on a Friday, and you want to change this to a Tuesday (3 days earlier) you must start a new strip 3 days earlier than usual. You may not have any bleeding during this time. You may then experience light or menstruation-like bleeding.

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

If you stop taking Femilux

You can stop taking this medicine whenever you want. If you do not want to become pregnant, ask your doctor for advice about other reliable methods of birth control. If you want to become pregnant, stop taking this medicine and wait for a menstrual period before trying to become pregnant. You will be able to calculate the expected delivery date more easily.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them. If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be due to this medicine, please talk to your doctor.

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 hives potentially with difficulty breathing (see also section 2 “Warnings and precautions”).

An increased risk of blood clots in your veins [venous thromboembolism (VTE)] or blood clots in your arteries [arterial thromboembolism (ATE)] is present for all women taking combined hormonal contraceptives. For more detailed information on the different risks from taking combined hormonal contraceptives please see section 2 “What you need to know before you take Femilux”.

The following is a list of the side effects that have been linked with the use of this medicine:

- **Common side effects** (may affect up to 1 in 10 people):
  - mood swings
  - headache
  - nausea
  - breast pain, problems with your periods, such as irregular periods, absence of periods

- **Uncommon side effects** (may affect up to 1 in 100 people):
  - depression, nervousness, sleepiness
  - dizziness, “pins and needles”
  - migraine, varicose veins, increased blood pressure
  - stomach ache, vomiting, indigestion, intestinal gas, inflammation of the stomach, diarrhoea
  - acne, itching, rash
  - aches and pains, for instance back pain, limb pain, muscle cramps

- vaginal fungal infection, pelvic pain, breast enlargement, benign breast lumps, uterine/vaginal bleeding (which usually subsides during continued treatment), genital discharge, hot flushes, inflammation of the vagina (vaginitis), problems with your periods, painful periods, reduced periods, very heavy periods, vaginal dryness, abnormal cervical smear, decreased interest in sex
- lack of energy, increased sweating, fluid retention
- weight increase

- **Rare side effects** (may affect up to 1 in 1,000 people):
  - candida (a fungal infection)
  - anemia, increase in the number of platelets in the blood
  - allergic reaction
  - hormonal (endocrine) disorder
  - increased appetite, loss of appetite, abnormally high concentration of potassium in the blood, abnormally low concentration of sodium in the blood
  - failure to experience an orgasm, insomnia
  - giddiness, tremor
  - eye disorders, for instance inflammation of the eyelids, dry eyes
  - abnormally rapid heartbeat
  - harmful blood clots in a vein or artery for example:
    - in a leg or foot (i.e. DVT)
    - in a lung (i.e. PE)
    - heart attack
    - stroke
    - mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA)
    - blood clots in the liver, stomach/intestine, kidneys or eye.

    The chance of having a blood clot may be higher if you have any other conditions that increase this risk (See section 2 for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot)
  - inflammation of a vein, nosebleed, fainting
  - enlarged abdomen, bowel disorder, feeling bloated, stomach hernia, fungal infection of the mouth, constipation, dry mouth
  - pain of bile ducts or the gallbladder, inflammation of the gallbladder
  - yellow brown patches on the skin, eczema, hair loss, acne-like inflammation of the skin, dry skin, lumpy inflammation of the skin, excessive hair growth, skin disorder, stretch marks on the skin, skin inflammation, light-sensitive skin inflammation, skin nodules.
  - difficult or painful sex, inflammation of the vagina (vulvovaginitis), bleeding following intercourse, withdrawal bleeding, breast cyst, increased number of breast cells (hyperplasia), malignant lumps in the breast, abnormal growth on the mucosal surface of the neck of the womb, shrinkage or wasting of the lining of the womb, ovarian cysts, enlargement of the womb
  - feeling generally unwell
  - weight loss

The following side effects have also been reported, but their frequency cannot be estimated from the available data:
- hypersensitivity,
- swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing. These are the symptoms of angioedema,
- erythema multiforme (rash with target-shaped reddening or sores).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Nederlands Bijwerkingen Centrum Lareb, Website: www.lareb.nl. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Femilux

Store below 30ºC.

Keep this medicine out of the sight and reach of children.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Femilux contains

- The active substances are drospirenone and ethinylestradiol.

  Each pink active film-coated tablet contains 3 milligram drospirenone and 0.02 milligram ethinylestradiol.

  The white placebo film-coated tablets do not contain active substances.

- The other ingredients are

  Pink active film-coated tablets: lactose monohydrate, pregelatinized starch (maize), povidone K-30 (E1201), croscarmellose sodium, polysorbate 80, magnesium stearate (E470b), poly (vinyl alcohol), titanium dioxide (E171), macrogol 3350, talc (E553b), yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172).

  White placebo film-coated tablets: lactose anhydrous, povidone K-30 (E1201), magnesium stearate (E572), poly (vinyl alcohol), titanium dioxide (E171), macrogol 3350, talc (E553b).

What Femilux looks like and contents of the pack

- Each blister of Femilux contains 24 pink, active film-coated tablets in the 1st, 2nd, 3rd and 4th rows of the strip and 4 white placebo film-coated tablets in row 4.
- Femilux tablets, both the pink and the white, are film-coated tablets; the core of the tablet is coated.
- Femilux is available in boxes of 1, 3, 6 and 13 blister strips, each containing 28 (24+4) tablets.

Not all pack sizes may be marketed

Houder van de vergunning voor het in de handel brengen
Egis Pharmaceuticals PLC
1106 Budapest, Keresztúri út 30-38.
Hongrije

Manufacturer
Laboratorios León Farma, S.A.
C/ La Vallina s/n, Pol. Ind. Navatejera.
24193 - Villaquilambre, León.
Spanje

Egis Pharmaceuticals PLC
1165 Budapest, Bökényföldi út 118-120.
Hungary

In het register ingeschreven onder
Femilux 3 mg/ 0,02 mg filmomhulde tabletten RVG 113240

This medicinal product is authorised in the Member States of the European Economic Area under the following names:

Nederland: Femilux
Czech Republic: Emona
Hungary: Femilux
Slovakia: Emona

Deze bijsluiter is voor het laatst goedgekeurd in december 2024.