Package leaflet: Information for the patient

Leonore 100 micrograms/20 micrograms coated tablets

levonorgestrel/ethinylestradiol

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").

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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Leonore is and what it is used for

Levonorgestrel/Ethinylestradiol is used
- for **prevention of pregnancy** (contraception).

- Each tablet contains a small amount of two different female hormones, namely levonorgestrel and ethinylestradiol.
- Contraceptive pills that contain two hormones are called "combination" pills.

2. What you need to know before you take Leonore

General Notes

Before you start using Leonore 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 start taking Leonore, 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 on your personal situation, may also carry out some other tests.
In this leaflet, several situations are described where you should stop using Leonore or where the reliability of Leonore may be decreased. In such situations, you should either not have sex or you should use other, non-hormonal contraceptive methods such as condoms. Do not use calendar or temperature methods. These methods can be unreliable because Leonore alters the monthly changes of body temperature and of the cervical mucus.

As with all oral 'pills' Levonorgestrel/Ethinylestradiol does not protect at all from a HIV infection, also called AIDS, or other sexually transmitted diseases.

Do not take Leonore:

You should not use Leonore 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 a **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) a **liver disease** and your liver function is still not normal
- 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**
- a **missed period** if the cause is undiagnosed.
- if you are **allergic** to ethinylestradiol, levonorgestrel or any of the other ingredients of this medicine (listed in section 6).

Do not use Leonore if you have hepatitis C and are taking medicines containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see also in section 'Other medicines and Leonore').

Additional information on special populations
Use in children
Leonore is not intended for use in females whose periods have not yet started.

Warnings and precautions
Talk to your doctor or pharmacist before taking Leonore.

When you should 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 clots' section below).

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

Tell your doctor if any of the following conditions apply to you.
If the condition develops or gets worse while you are using Leonore, you should also tell your doctor. These risks may require particular monitoring during intake, which your doctor will explain in detail:
- **persistently elevated blood pressure** values
- **diabetes** (diabetes mellitus)
- **jaundice** and/or **itching** due to bile stasis
- **gallstones**
- 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 uraemic 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 Leonore.
- if you have **an inflammation in the veins under the skin** (superficial thrombophlebitis)
- if you have **varicose veins**
- **impaired formation of blood pigment** (porphyria)
- a form of **St. Vitus's dance** (Sydenham's chorea)
- **bladder rash** during pregnancy (herpes gestationis)
- a form of **hearing loss** (otosclerosis)
- **depressive mood**
- **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.
- **epilepsy**
- existing or preceding **brown-yellowish pigmented moles** (chloasma, also called pregnancy stretch marks, predominantly in the face). In this case it is recommended to avoid direct sunlight or ultraviolet light.
- **migraines.**

BLOOD CLOTS

Using a combined hormonal contraceptive such as Leonore 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 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 Leonore 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: o pain or tenderness in the leg which may be felt only when standing or walking o increased warmth in the affected leg o 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	Pulmonary embolism

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').	
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 • fullness, indigestion or choking feeling • upper body discomfort radiating to the back, jaw, throat, arm and stomach • sweating, nausea, vomiting or dizziness • extreme weakness, anxiety, or shortness of breath • rapid or irregular heartbeats.	Heart attack
• sudden weakness or numbness of the face, arm or leg, especially on one side of the body • sudden confusion, trouble speaking or understanding • sudden trouble seeing in one or both eyes • sudden trouble walking, dizziness, loss of balance or coordination • sudden, severe or prolonged headache with no known cause • loss of consciousness or fainting with or without seizure. Sometimes the symptoms of stroke can be 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 Leonore 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 Leonore 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 such as Leonore, about 5-7 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 and are not pregnant	About 2 out of 10,000 women
Women using a combined hormonal contraceptive pill containing **levonorgestrel**	About 5-7 out of 10,000 women
Women using Leonore	About 5-7 out of 10,000 women

Factors that increase your risk of a blood clot in a vein
The risk of a blood clot with Leonore 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 Leonore may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Leonore, 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 Leonore needs to be stopped.

If any of the above conditions change while you are using Leonore, 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 Leonore is very small but can increase:

- with increasing age (beyond about 35 years)
- **if you smoke.** When using a combined hormonal contraceptive like Leonore 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 Leonore, 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.

'Pill' and cancer
Breast cancer is somewhat more frequently diagnosed in women taking the 'pill' than in women of the same age who do not practice birth control with the 'pill'. After discontinuation of the 'pill', breast cancer figures slowly become more alike again, and after 10 years, there is no difference ascertainable between former 'pill users' and other women.

As breast cancer is relatively low in women below 40 years of age, the number of additional cases of breast cancer in previous or current users of the 'pill' is small in comparison with the overall risk of breast cancer.

It is important, that all women, in particular those over 35 years of age, have regular breast examinations while taking Leonore**.** You should contact your doctor if you feel any lump.

In rare cases, benign liver tumours and, even more rarely, malignant liver tumours were diagnosed in 'pill' users. In some few cases, these tumours led to life-threatening inner bleeding. If you suddenly develop severe abdominal pain, you must consult your doctor without delay.

Cancer of the cervix has somewhat more frequently been reported in women taking the 'pill' over a long-term period. However, there continues to be controversy to which extent sexual behaviour and other factors such as human papilloma virus contribute to this finding.

Psychiatric disorders
Some women using hormonal contraceptives including Leonore 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.

Reduced efficacy
The contraceptive effect can be reduced due to forgetting to take the 'pill', vomiting, bowel diseases with severe diarrhoea or using together with other medicines.

Irregular bleeding
All 'pills' can lead to irregular bleeding (spotting or breakthrough bleeding), particularly in the first months. Spotting and breakthrough bleeding were observed in half the users during the first 6 intake cycles. Please consult your doctor if this irregular bleeding continues to occur after 3 months.

No withdrawal bleeding may occur in some users in the intake-free interval. If you have taken all the tablets correctly, pregnancy is improbable. However if the pill was not taken as prescribed prior the first missing

withdrawal bleeding or the withdrawal bleeding has not appeared already for the second time, you may be pregnant. Contact your doctor immediately. Do not start the next strip until a pregnancy has been excluded.

If you plan a pregnancy
Folic acid levels in the blood may decrease during use of the 'pill'. Folic acid deficiency can lead to impaired development of brain and spinal cord (neural tube defects) in the unborn child. If you stop taking Leonore because you want to become pregnant, it is recommended that you eat food rich in folic acid (vegetables, fruit, wholemeal products) and that you take folic acid tablets before and after conception. Ask your doctor or pharmacist for a suitable preparation.

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

Also inform any doctor or dentist who prescribes other medicines (or the pharmacist) that you are taking Leonore. These can tell you if you need to use additional contraceptive precautions (e.g. condoms) and, if so, how long.

Some medicines can have an influence on the blood levels of Leonore and can make it less effective in preventing pregnancy, or can cause unexpected bleeding. These include:
- Medicines for the treatment of:
  - **gastrointestinal motility disorders** (e.g. metoclopramide)
  - epilepsy such as hydantoins (e.g. **phenytoin**), **barbiturates, barbexaclone, primidone, carbamazepine, oxcarbazepine, topiramate and felbamate**
  - tubercolosis (e.g. **rifampicin, rifabutin**)
  - fungal infections (**griseofulvin, azole antimycotics e.g. itraconazole, voriconazole, fluconazole)**
  - bacterial infections (macrolide antibiotics, e.g. **clarithromycin, erythromycin**)
  - certain heart disease, high blood pressure (calcium channel blockers, e.g. **verapamil, diltiazem**)
  - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as **ritonavir, nelfinavir, nevirapine, efavirenz**)
  - arthritis, arthrosis (**etoricoxib**)
  - high blood pressure in the blood vessels of the lungs (**bosentan**)
- **medicines containing St. John's wort**
- **grapefruit juice.**

If you are treated with one of the above-named medicines, you should use additional non-hormonal contraceptive methods such as condoms in addition to Leonore during this period and for 28 days afterwards.

If you must take one of these medicines for a longer-term period, please ask your doctor for advice. If necessary, you should use another non-hormonal contraceptive method in this case.

If use of a barrier method is necessary for longer than the current pack of 'pills' lasts, you should start the next pack of Leonore immediately, without observing a 7-day tablet-free interval.

Leonore and other 'pills' can also influence the metabolism of other medicines.

The efficacy or tolerability of the following medicines may be impaired due to Levonorgestrel/Ethinylestradiol:
- **ciclosporin**, a medicine to suppress the immune system
- **theophylline**, a medicine for the treatment of asthma
- **tizanidine** (used to treat muscle pain and / or muscle cramps)
- **lamotrigine**, a certain medicine against epilepsy
- **melatonin** (used to treat insomnia)
- **midazolam** (used for sedation)
- **troleandomycin**, a medicine to treat bacterial infections. The concomitant use of the 'pill' and the antibiotic troleandomycin can increase the risk of biliary thrombus.

Please take note of the information provided in the package leaflets of any other prescribed medicines.

In women with diabetes, the need for blood sugar-lowering agents (e.g. insulin) may be changed.

Do not use Leonore if you have Hepatitis C and are taking medicines containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir, as these medicines 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 medicines. Leonore can be restarted approximately 2 weeks after completion of this treatment. See section "Do not use Leonore".

Pregnancy and breast-feeding

- **Pregnancy**

Do not use Leonore if you are pregnant.

Pregnancy must be excluded before starting Leonore. If pregnancy occurs during use, you must stop taking Leonore immediately and consult your doctor.

Breast-feeding
You should not use Leonore when breast-feeding, as the quantity of milk can be reduced and the composition of the milk changed. Small amounts of the active substances and/or their degradation products can pass into mother's milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
No special precautionary measures are necessary.

Leonore contains lactose and sucrose
If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose or sucrose), contact your doctor before taking this medicine.

Laboratory tests
If you need a blood test, tell your doctor that you are taking Leonore. Indeed use of the 'pill' can influence the results of certain laboratory tests.

3. How to take Leonore

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by the doctor, the recommended dose is 1 tablet daily.

Always take the tablets at about the same time of the day, if necessary with 1 glass of water. Further intake is in the direction of the arrow, according to the marked day of the week until all the 21 tablets have been taken.

Afterwards, do not take tablets for 7 days. Bleeding (withdrawal bleeding) should start in this interval, usually on day 2 or 3 after you have taken the last tablet.

Start taking tablets from the next foil strip on day 8, irrespective whether bleeding persists or not. You always start with a new foil strip on the same day of the week and have your bleeding on about the same days every month.

Note: Correct use ensures birth control as from the first day of intake.

Starting intake from the first foil strip

- No intake of the 'pill' in the preceding month:
  Start intake on the first day of your cycle. This is the first day of your monthly bleeding. If you start taking Leonore between day 2 and 5, further contraceptive measures such as condoms are necessary in the first 7 days. Always remove the tablet from the marked place with the corresponding day of the week.

- Change from another combination preparation ('pill', vaginal ring or transdermal patch):
  You can start Leonore preferably on the day after the last active tablet (the last tablet containing the active substances) of your previous pill or the day after removal of the vaginal ring or transdermal patch, but at the latest on the day after the tablet-free days of your previous pill (or after the last inactive tablet of your previous pill) or after the ring-free or patch-free break.

- Change 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 use extra protective measures (for example, a condom) for the first 7 days of tablet-taking.
- After birth of a child:
  Start taking Leonore not earlier than 21-28 days after the birth. If you start taking Leonore at a later time, you must use further contraceptive measures such as condoms in the first 7 days. However, if you have already had sexual intercourse, pregnancy must be excluded before use of Leonore is started, or you should wait for the first menstrual bleeding to occur. If you are breast-feeding and want to take Leonore at the same time, you should also ask your doctor.

- After miscarriage or terminated pregnancy:
  Ask your doctor for advice.

Please contact your doctor or pharmacist if you have the impression that the effect of Leonore is too strong or too weak.

If you take more Leonore than you should
There are no reports of serious harmful results of taking too many Leonore tablets.

The following symptoms may occur: nausea, vomiting (as a rule, after 12 – 24 hours, and possibly persistent for up to several days), breast tenderness, drowsiness, abdominal pain, sleepiness/tiredness. Women and young girls may experience vaginal bleeding. Even girls who have not had their first menstruation and have accidentally taken this medicine may experience such bleeding.

If you have taken a larger amount, you must consult a doctor who can treat the symptoms.

If you forget to take Leonore
Time of intake exceeded by less than 12 hours:
Contraception of Leonore is still ensured. Immediately take the forgotten tablet. Afterwards, follow the usual rhythm of intake.

Time of intake exceeded by more than 12 hours:
Contraception is no longer ensured. The risk of unintentional pregnancy is particularly high if a tablet has been forgotten at the beginning or the end of the foil strip. In this case, proceed as described below.

- **More than 1 tablet** of the current foil strip **forgotten**: Ask your doctor or pharmacist for advice.
- **Only 1 tablet forgotten in week 1:**
  Take the missed tablet immediately even if you have to take 2 tablets at the same time. Then continue intake as usual. However, **further contraceptive measures** such as condoms are necessary in the next 7 days. There is a risk of pregnancy, if you had had sexual intercourse in the week before forgetting the tablet. Immediately inform your doctor in this case.
- **Only 1 tablet forgotten in week 2:**

Take the missed tablet immediately even if you have to take 2 tablets at the same time. If the tablets have been taken correctly in the preceding 7 days, the contraceptive effect is ensured. No further protective measures are necessary. If this was not the case further contraceptive measures such as condoms are necessary in the next 7 days.

- **Only 1 tablet forgotten in week 3:**
  Only if you have **taken the tablets correctly in the preceding 7 days** and one of the two following possibilities is given, no further contraceptive measures are necessary. If this was not the case, the first of these two options should be followed and further contraceptive measures such as condoms must be used for the next 7 days.

  1. Immediately make up for the forgotten tablet even if you thus take 2 tablets at the same time. Take the next tablets as usual. Omit the intake-free break, and directly start taking the tablet from the next foil strip. A withdrawal bleeding will probably not occur, but spotting and breakthrough bleeding are possible during intake of the tablets from the second foil strip.

  Or

  2. Discontinue intake from the current foil strip immediately, and stop intake for a maximum of 7 days, including **the forgotten day.** Then start with the new foil strip as usual while it is possible that you shorten the intake-free break.

If no bleeding occurs in the intake-free break after you have forgotten Leonore, it may be possible that you are pregnant. Consult your doctor before starting with a new foil strip.

In case of vomiting or severe diarrhoea
If you vomit within 3-4 hours after taking a 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, take another tablet from a reserve strip as soon as possible. If possible take it within 12 hours of when you normally take your pill. If that is not possible or 12 hours have passed, you should follow the advice given under “If you forget to take Leonore”.

If you want to postpone your bleeding
In this case, immediately start with a new foil strip without intake-free break. You can continue intake until all tablets of the second foil strip have been used up or stop it earlier if you wish your bleeding to start. During intake from the second foil strip, breakthrough bleeding or spotting can occur. Start taking the tablets from the next foil strip after the usual intake-free break for 7 days.

If you want to change the weekday of the beginning of your bleeding
In this case, shorten, but never prolong the normal intake-free break as shown in the following example: Your bleeding usually appears on Friday, and it should start 3 days earlier, i.e. Tuesday. In this case, start tablet taking 3 days earlier than usual. In case of short intake-free breaks of 3 days or less, withdrawal bleeding may fail to appear, but breakthrough bleeding and spotting may occur during intake of the tablets from the new foil strip.

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 Leonore, please talk to your doctor.

An increased risk of blood clots in the veins (venous thromboembolism (VTE)) or blood clots in the arteries (arterial thromboembolism (ATE)) is present for all women using 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 Leonore’.

Serious side effects – see a doctor straight away
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 "Warnings and precautions").

Rare side effects (may affect up to 1 in 1,000 people)
- 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).

Very rare side effects (may affect up to 1 in 10,000 people)
- painful swelling of skin and mucous membranes (angioedema)
- very severe allergic reactions with respiratory and circulatory symptoms.

Not known: frequency cannot be estimated from the available data:
- inflammation of the optic nerve which may lead to partial or complete loss of vision
- worsening of varicose veins
- pancreatitis in the case of concomitant severe disorder in the fat metabolism
- gall bladder disorder, including gall stones
- a form of hardness of hearing (otosclerosis)
- worsening of a depression
- worsening of symptoms of hereditary and acquired angioedema.

For further severe side effects such as formation of blood clots, increased blood pressure, tumours of liver, breast cancer, chronic inflammatory bowel diseases (Crohn's disease, ulcerative colitis), impaired formation of blood pigment (porphyria), immune system disease as systemic lupus erythematosus (where the body attacks and injures its own organs and tissues), herpes in late pregnancy, rapid involuntary jerking or twitching movements (Sydenham's chorea), a form of kidney failure (haemolytic-uraemic syndrome, a condition which occurs after diarrhoea caused by E.coli) or jaundice and/or itching due to bile stasis (see section 2).

Less serious side effects
Very common side effects (may affect more than 1 in 10 people) associated with the intake of the 'pill' are headache (including migraine), spotting and intermenstrual bleeding.

Common side effects (may affect up to 1 in 10 people)
- vaginal inflammation including fungal infection (candidiasis)
- mood swings, including depression
- nervousness
- drowsiness
- vertigo
- headache
- visual disturbances
- nausea
- pain in the abdomen
- acne
- breast pain
- breast tenderness
- menstrual pain

- changed strength of menstrual bleeding
- increased secretion from the vagina
- non-appearance of the menstrual bleeding
- putting on weight.

Uncommon side effects (may affect up to 1 in 100 people)
- changed appetite (increase or decrease)
- fluid retention
- decrease in interest in sex
- migraine
- diarrhoea
- vomiting
- cramps in the abdomen
- flatulence
- skin rash which may be itchy
- brown-yellowish pigmented moles in the face (chloasma), possibly persistent
- increased body and face hairs
- hair loss
- rash
- hives
- breast enlargement
- changed blood lipid values.

Rare side effects (may affect up to 1 in 1000 people)
- signs of hypersensitivity or allergic reactions
- increased blood glucose level (glucose intolerance)
- increase in interest in sex
- intolerance to contact lenses
- nodal fever (erythema nodosum)
- skin reddening with formation of blisters and nodules (erythema multiforme)
- vaginal or breast discharge
- losing weight
- decrease in the folic acid levels in the blood.

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 the national reporting system: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Leonore

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 outer package and the blister after "EXP". The expiry date refers to the last day of that month.

Do not store above 30°C.

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 Leonore contains

- The active substances are levonorgestrel and ethinylestradiol.
  Each coated tablet contains 100 micrograms of levonorgestrel and 20 micrograms of ethinylestradiol.
- The other ingredients are lactose monohydrate, magnesium stearate, maize starch, povidone K25, calcium carbonate, carnauba wax, macrogol 6000, povidone K90, sucrose and talc.

What Leonore looks like and contents of the pack
The coated tablets are round, white, biconvex, coated tablets.

The coated tablets are packed in PVC/PVDC/aluminium blister and inserted in a carton box.
Each blister contains 21 coated tablets.

Pack sizes:
1 x 21, 3 x 21, 6 x 21, and 50 x 21 coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.
LEK S.A., ul. Domaniewska 50 C, 02-672 Warszawa, Poland.
Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.
Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland.
Haupt Pharma Münster GmbH, Schleebrüggenkamp 15, 48159 Münster, Germany.

This medicinal product is authorised in the member states of the EEA under the following names:
DE: Leona HEXAL 0,10 mg/0,02mg überzogene Tabletten
IE: Leonore 100 micrograms/20 micrograms coated tablets

This leaflet was last revised in 10/2022.