Approved Patient Information Leaflet for Medicines for Human Use:

LEYLA

SCHEDULING STATUS: S4

LEYLA 3 mg/0,02 mg film-coated tablets

Each active film -coated tablet (pink) contains

3 mg of drospirenone and 0,02 mg of ethinyl estradiol.

Each inactive (placebo) film-coated tablets (white) contains

no active ingredients.

LEYLA contains sugar (lactose):

Each LEYLA active film-coated tablet (pink) contains 41,8 mg lactose as 44 mg lactose monohydrate.

Each LEYLA inactive film-coated tablet (white) contains 89,5 mg lactose as 89,5 mg anhydrous lactose.

Contains less than 1 mmol sodium per dose.

Each LEYLA active film-coated tablet (pink) contains 0,225 mg (0,0098 mmol) sodium, that is to say essentially 'sodium-free'.

Each LEYLA inactive film-coated tablet (white) is 'sodium-free'.

Read all of this leaflet carefully before you start taking LEYLA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- LEYLA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LEYLA is and what it is used for
2. What you need to know before you take LEYLA
3. How to take LEYLA
4. Possible side effects
5. How to store LEYLA
6. Contents of the pack and other information

1. What LEYLA is and what it is used for

LEYLA is a combined oral contraceptive ("the combined pill") and is used to prevent pregnancy.

It consists of 24 pink tablets that contain a small amount of two different female hormones, namely drospirenone (3 mg) and ethinyl estradiol (0,02 mg) and 4 white tablets that contain no active substances and are also called placebo or inactive tablets.

LEYLA can also be used to treat moderate acne and premenstrual dysphoric disorder (a health problem that is similar to premenstrual syndrome (PMS), which causes severe depression, irritability, or anxiety before menstruation in women).

2. What you need to know before you take LEYLA

General notes

Before you start using LEYLA, 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 LEYLA, 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 LEYLA, or where the reliability of LEYLA may be decreased. In such situations you should either not have sex or you should take extra non-hormonal contraceptive precautions, e.g., use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because LEYLA alters the monthly changes of body temperature and of cervical mucus.

LEYLA does not protect against HIV infection (AIDS) or any other sexually transmitted disease. Additional barrier contraceptive measures are needed to prevent transmission of HIV and STDs infections.

Do not take LEYLA

Do not take LEYLA 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 are hypersensitive (allergic) to ethinyl estradiol or drospirenone, or any of the other ingredients of LEYLA (listed in section 6). This may cause itching, rash or swelling
- 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, activated protein-C resistance (Factor V Leiden) or antiphospholipid antibodies (anticardiolipin antibodies,

lupus anticoagulant) as these blood clotting disorders may predispose you to blood clots in your blood in your veins or arteries.

- 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 (high blood levels of homocysteine, a type of amino acid produced when proteins are broken down which can contribute to arterial damage and blood clots in your blood vessels)
- if you have (or have ever had) a type of migraine called ‘migraine with aura’ (this is a recurring headache that strikes after or at the same time as sensory disturbances called aura. These sensory disturbances can include flashes of light, blind spots and other vision changes or speech disability or weakness, numbness or tingling in any part of your body)
- if you have (or have ever had) a 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 (an abnormal growth of tissue, whether benign or malignant) 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 pregnant or think you might be pregnant
- if you have depression that is not well-controlled by treatment of if you have previously had depression with the use of a hormonal contraceptive such as LEYLA
- if you have hepatitis C and are taking the medicines containing ombitasvir/paritaprevir/ritonavir and dasabuvir (see also in section 2 “Other medicines and LEYLA”).

Warnings and precautions

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 clots’ section below).

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

Take special care with LEYLA

Talk to your doctor before taking LEYLA:

In some situations, you need to take special care while using LEYLA or any other combination pill, and your doctor may need to examine you regularly. If the condition listed below develops, or gets worse while you are using LEYLA, you should tell your doctor.

- if you smoke
- if you are overweight
- if a close relative has or has ever had cancer
- if a close relative ever had stroke or heart attack at young age
- if you have a disease of the liver or the gallbladder

- if you have diabetes
- if you have high blood pressure
- if you have problem with your heart (valve disorder)
- if you have depression
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- 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 epilepsy (see in section 2 "Other medicines and LEYLA")
- if you have disease of your immune system called systemic lupus erythematosus (SLE)
- 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, symptoms include severe upper stomach pain, often with nausea and vomiting)
- 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 LEYLA
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis)
- if you have varicose veins (large, swollen veins that often appear on the legs and feet and can cause symptoms like swollen, aching, and painful legs)
- 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, yellowing of the skin or eyes (jaundice), itching of the whole body (pruritis), 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 a discolouration (golden brown pigment patches) of the skin especially on the face or neck known as “pregnancy patches” (chloasma). If so, avoid direct exposure to sunlight or ultraviolet light
- if you have hereditary angioedema (the swelling of the deeper layers of the skin, caused by a build-up of fluid), products containing ~~o~~estrogens may cause or worsen the symptoms. You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or pharynx and/or difficulty swallowing or hives together with difficulty breathing
- if you have increased potassium serum levels.

If any of the above conditions appear for the first time, recur or worsen while taking LEYLA, you should contact your doctor.

Blood clots

Using a combined hormonal contraceptive such as LEYLA increases your risk of developing a blood clot (also called a thrombosis) compared with not using one. In rare cases a blood clot can block 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 LEYLA 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 (DVT)
• 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	Pulmonary embolism (PE)

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	Stroke

• 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.	
• 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 or artery

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 (PE).
- Very rarely a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

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.

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 LEYLA your risk of a blood clot returns to normal within a few weeks.

Factors that increase your risk of a blood clot in an artery or vein

It is important to note that the risk of a blood clot, heart attack or stroke from using LEYLA is very small but can increase:

- with increasing age (beyond about 35 years)
- **if you smoke**. When using a combined hormonal contraceptive like LEYLA, 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 very overweight (body mass index or BMI over 30 kg/m^2)
- 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 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 LEYLA may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop LEYLA ask your doctor when you can start using it again
- if you gave birth less than a few weeks ago.

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

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 LEYLA, 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.

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 drospirenone/ethinyl estradiol such as LEYLA 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.

LEYLA and antibiotics

You must take special care when LEYLA is used together with an antibiotic (medicine used for the treatment of an infection). The antibiotic can cause LEYLA to become ineffective to prevent conception from occurring in an act of intercourse and hence you may fall pregnant (see in section 2 “Other medicines and LEYLA”).

You will need to take additional contraceptive precautions to prevent falling pregnant due to the antibiotic’s interference with LEYLA’s effectiveness. For maximal protection, additional barrier contraception (e.g. condoms) is recommended for the duration of antibiotic therapy and for seven days after discontinuation of the antibiotic. If the period during which the barrier method is used runs beyond the end of the active tablets in the LEYLA pack, the

placebo tablets (i.e. the white tablets in 4th row) should be left out and the next pack of LEYLA should be started with the active tablets (i.e. pink tablets) on the upper left of the pack.

If you are on long-term antibiotic therapy, you need to only take extra precautions for the first two weeks of antibiotic therapy.

Spotting (unexpected uterine bleeding in small amounts) and breakthrough bleeding (uterine bleeding at unexpected time during the menstrual cycle in larger amounts that require use of a tampon or a sanitary napkin) are possible signs of diminished contraceptive effectiveness of LEYLA when used together with an antibiotic.

Bleeding between periods

During the first few months that you are taking LEYLA, you may have unexpected bleeding (bleeding outside the 4 inactive tablet 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 4 inactive (placebo) tablet days

If you have taken all the light pink active tablets correctly, 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.

Laboratory tests

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

Children and adolescents

LEYLA is not intended for use in females whose menstrual cycle has not yet started.

Other medicines and LEYLA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines). The use of LEYLA with some medicines can cause undesirable interactions and may make LEYLA less effective in preventing pregnancy.

Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you take LEYLA. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long, or, whether the use of another medicine you need must be changed.

Medicines that can have an influence on the blood levels of the active ingredients in LEYLA

Some medicines can

- lower the blood levels of the active ingredients (i.e., ethinyl estradiol and drosperinone) in LEYLA and
- make it less effective in preventing pregnancy and
- cause unexpected bleeding.

You will need additional precaution to prevent pregnancy, ask your doctor or pharmacist about the duration of precaution required with each of these medicines.

These include medicines used for the treatment of:

- epilepsy (e.g., primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate)
- tuberculosis (e.g., rifampicin)
- HIV and Hepatitis C Virus (HCV) infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efavirenz)
- fungal infections (e.g. griseofulvin)
- high blood pressure in the blood vessels in the lungs (bosentan)
- depressive moods (herbal medicine containing St. John's Wort [*Hypericum perforatum]*)
- bacterial infections (antibiotics e.g., penicillins, tetracyclines such as doxycycline [also used to prevent malaria], minocycline etc). You will need to take additional contraceptive precautions to prevent falling pregnant (see in section 2 "LEYLA and antibiotics").

Some medicines can increase the blood levels of the active ingredients in LEYLA.

These include medicines used for the treatment of:

- fungal infections (e.g., ketoconazole)
- arthritis, arthrosis (etoricoxib).

Some medicines can increase the levels of potassium in your blood when used together with LEYLA.

These include medicines used for the treatment of:

- high blood pressure (bosentan, angiotensin-II-receptor antagonists, potassium-sparing diuretics, and aldosterone antagonists).

You may do not feel symptoms of high potassium. Having too much potassium in your blood can be dangerous as it can even cause a heart attack. If you do feel symptoms of high potassium in your blood, such as feeling tired or weak, feeling sick to the stomach (nausea), having muscle pains or cramps, having trouble breathing, unusual heartbeat, chest pains,

please contact your doctor immediately or go to the casualty department of your nearest hospital.

LEYLA may influence the effect of other medicines, e.g.

- medicines containing ciclosporin (immunosuppressive medicine used for the prevention of rejection in organ transplants. It is also used to reduce pain, swelling and stiffness in rheumatoid arthritis and to treat a number of other autoimmune and inflammatory conditions, including psoriatic arthritis and lupus). This could lead to increased concentrations and side effects of ciclosporin.
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures due to the lowering in lamotrigine concentrations)
- theophylline (used to treat breathing problems). This could lead to increased concentrations and side effects of theophylline.
- tizanidine (used to treat muscle pain and/or muscle cramps). This could lead to increased concentrations and side effects of tizanidine.

Do not use LEYLA if you have hepatitis C and are taking the medicines containing ombitasvir/paritaprevir/ritonavir and dasabuvir 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 with these medicines. LEYLA can be restarted approximately 2 weeks after completion of this treatment. See section 2 “Do not take LEYLA”.

LEYLA with food and drink

LEYLA may be taken with or without food, if necessary with a small amount of water.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy

If you are pregnant, you must not take PRODUCT NAME. If you become pregnant or suspect that you are pregnant while taking LEYLA, you must stop immediately and contact your doctor. If you want to become pregnant, you can stop taking LEYLA at any time (see also in section 3 “If you stop taking LEYLA”).

Breastfeeding

Use of LEYLA is not recommended during breastfeeding. If you want to take LEYLA while you are breastfeeding, you should contact your doctor.

Driving and using machines

It is not always possible to predict to what extent LEYLA may interfere with your daily activities. You may experience undesirable effects such as sleepiness, dizziness, or a sensation of feeling off balance (vertigo) during treatment (see section 4. Possible side effects). You should ensure that you do not engage in the above activities until you are aware of the measure to which LEYLA affects you.

LEYLA contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

LEYLA contains sodium

LEYLA contains less than 1 mmol sodium per dose.

Each LEYLA active film-coated tablet (pink) contains 0,225 mg (0,0098 mmol) sodium, that is to say essentially 'sodium-free'.

Each LEYLA inactive film-coated tablet (white) is 'sodium-free'.

3. How to take LEYLA

Do not share medicines prescribed for you with any other person.

Always take/use LEYLA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take LEYLA every day for 28 days

LEYLA comes in a blister strip containing 24 active pink film-coated tablets and 4 white inactive film-coated tablets, each marked with a day of the week (see section 6 “What LEYLA looks like and contents of the pack”).

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

Take one tablet of LEYLA every day around the same time.

- Start by taking the active pink tablet marked with the correct day of the week (please see Preparation of strip)
- Follow the direction of the arrows on the strip for the correct order.
- Take one tablet each day, until you have finished all 24 active pink tablets (see Method of administration)

- Then have the four inactive white tablets taking one inactive tablet each day for the last four days

Do not confuse the tablets

Take a pink tablet for the first 24 days and then a white tablet for the last 4 days. Within a few days of starting the inactive tablets from the strip, you should have a withdrawal bleed like a period. This bleed may not have finished before the next pack is started.

You must then start taking your next strip of LEYLA straight away after the four days of inactive tablets even if you are still bleeding. There is therefore no gap between two strips. Always start the new strip on time.

You don’t need to use extra contraception during these four inactive tablet days as long as you have taken your tablets correctly.

Preparation of the strip

To help you keep track, there are 7 stickers each with 7 days of the week for each strip of LEYLA. 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 week sticker along the top of the blister where it reads “Place day label here”, so that the first day is above the tablet marked “1”. 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 start (so-called withdrawal bleeding). This usually starts on the 2nd or 3rd day

after the last pink active tablet of LEYLA. 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 LEYLA 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 LEYLA on the first day of the cycle (that is, the first day of your period). If you start LEYLA 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 LEYLA 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 inactive 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 (minipill, 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 taking

LEYLA.

After a miscarriage or abortion

If you have had a miscarriage or abortion during the first three months of pregnancy, your doctor may tell you to start taking LEYLA straight away. This means that you will have contraceptive protection with your first pill.

After miscarriage in the second 3 months or after having a baby

You can start LEYLA between 21 and 28 days after having a baby or miscarriage in the second 3 months. If you start later than day 28, you must use a so-called barrier method (for example, a condom) during the first seven days of taking LEYLA.
If, after having a baby, you have had sex before starting LEYLA (again), you must first be sure that you are not pregnant or you must wait until your next period.

If you are breastfeeding and want to start LEYLA after having a baby

Use of LEYLA is generally not advisable when a woman is breastfeeding (Read the section on “Breastfeeding”, in section 2 “What you need to know before you take LEYLA”). If you want to take the pill while you are breastfeeding you should contact your doctor.

Method of administration

Swallow each tablet whole, with water if necessary. Do not chew the tablet. You may take the tablets with or without food, but you should take the tablets every day around the same time.

If you take more LEYLA than you should

There are no reports of serious harmful results of taking too many drospirenone 3 mg and ethinyl estradiol 0,02 mg tablets.

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 LEYLA tablets, or you discover that a child has taken some, consult your doctor or pharmacist for advice. If neither is available, contact the nearest hospital or poison centre.

If you forget to take LEYLA

The last 4 white 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 LEYLA. 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 12 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 12 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 to the following rules:

- ***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 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. However, if this is not the case, or if you have missed more than 1 tablet, you will need to use extra precautions for 7 days.

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

  You can choose between two possibilities. Provided that in the 7 days preceding the first missed tablet you have taken all tablets correctly. If this is not the case, you should follow the first of these two options, and use extra precautions for the next 7 days as well.

  1. Take the forgotten tablet as soon as you remember, even if that means 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 as soon as you have taken the last active (pink) tablet (the starting day will be different).

Most likely, you will have a period at the end of the second strip - while taking the white inactive 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 inactive 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 inactive 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 first inactive tablet period, you may be pregnant. You must contact your doctor before you start the next strip.

What to do in the 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 active pink tablet from another reserve pack as soon as possible. If possible, take it within 12 hours of when you normally take your pill. If this is not possible or 12 hours have passed, you should follow the advice given under “If you forget to take LEYLA”.

Vomiting or diarrhoea while taking tablets from the inactive white tablets does not have an influence on the contraceptive reliability.

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 LEYLA and finishing 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 should 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 4 inactive tablet days. If you must change this day, reduce the number of inactive days – when you take the white placebo tablets - (but never longer – 4 days is the maximum). For example, if you start the 4 inactive tablet days 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. If you make the inactive tablet period very short (for example 3 days or less), 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 LEYLA

You can stop taking LEYLA 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 LEYLA 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

LEYLA can have side effects.

Not all side effects reported for LEYLA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LEYLA, please consult your health care provider for advice.

If any of the following happens, stop taking LEYLA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- **Severe allergic reactions/hypersensitivity reactions:** sudden swelling of your face, lips, mouth, tongue or throat, difficulty breathing or low blood pressure which may cause fainting or collapse.
- **Erythema multiforme:** severe condition of the skin that may affect the mouth and other parts of the body; symptoms include red, bull's-eye-shaped (having a pink-red centre surrounded by a pale ring border and an outer pink-red ring) often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body.
- **Signs of blood clot** include sudden weakness or numbness in one side or part of your body, pain and tightness in the chest, stabbing pain when you breathe, dizziness or fainting, coughing for no apparent reason, pain or swelling in your leg, any sudden changes to your sense of hearing, speech, sense of smell, taste or touch. 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, kidneys, eye (this can cause immediate loss of vision or painless blurring of vision which can progress to loss of vision); or blood clots blocking other blood vessels in limbs (which can cause swelling and slight blue discolouration of an extremity) or in your stomach and intestines (this can cause severe abdominal pain and usually requires emergency surgery)
- **Signs of breast cancer** include dimpling of the skin, changes in the nipple, any lumps you can see or feel, unusual vaginal bleeding
- **Signs of cancer of the cervix** include vaginal discharge that smells and/or contains blood, unusual vaginal bleeding, pelvic pain, painful sex
- **Signs of severe liver problems** include severe pain in your upper abdomen, yellow skin or eyes (jaundice), inflammation of the liver, your whole body starts itching.

These are all very serious side effects. If they occur, you may have had a serious reaction to LEYLA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- abnormally rapid heartbeat (tachycardia)
- inflammation of vein, vascular disorder, nosebleed, fainting
- enlarged, swollen, or twisting veins
- asthma (tightness in the chest, wheezing and difficulty breathing)
- increased blood pressure, decreased blood pressure
- pain of bile ducts (pain that comes and goes and occurs when a gallstone is being passed and is blocking a bile duct) or inflammation of the gallbladder (which can cause severe pain in the upper-right or centre belly, pain that spreads to your right shoulder or back, tenderness over your belly when it's touched, nausea, vomiting, fever and bloating)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- depressive mood, emotional lability (rapid, often exaggerated changes in mood, where strong emotions or feelings (uncontrollable laughing or crying, or heightened irritability or temper) occur)
- headache, migraine (throbbing headache, usually affecting one side of the head and often accompanied by nausea, vomiting and sensitivity to light)
- nausea (feeling sick)
- breast pain, menstrual problems, bleeding between periods, thick whitish vaginal discharge, vaginal yeast infection.

Less frequent side effects:

- increased appetite
- anorexia (obsession of what they eat)
- increased potassium level in blood (this can lead to muscle fatigue, weakness, paralysis, abnormal heart rhythms, nausea). The potassium level will be seen in a blood test
- decreased sodium level in blood. The sodium level will be seen in a blood test
- fluid retention, changes in body weight
- changes in sexual drive
- nervousness, drowsiness, inability to fall asleep
- failure to experience an orgasm
- hearing impairment
- dyspepsia (indigestion), flatulence (intestinal gas), gastritis (inflammation of the stomach, symptoms include pain, nausea, vomiting, vomiting blood, blood in the bowel motions), diarrhoea

- enlargement of abdomen, gastrointestinal disorder, abdominal fullness (due to excessive gas build up in the digestive tract)
- hiatus hernia (protrusion of upper part of stomach into the chest)
- fungal infection in mouth and throat
- constipation, dry mouth
- acne, severe itching, rash, chloasma (discolouration of the skin especially of the face or neck known as “pregnancy patches”), alopecia (hair loss), dermatitis acneiform (skin rash with a flat discoloured area or raised bumps like acne), dry skin, erythema nodosum (skin condition characterized by painful reddish skin nodules), excessive hair growth in a defined area, skin disorder, white markings on skin, contact dermatitis (local skin reaction characterised by skin redness, swelling and itching, pain or burning sensation), light-sensitive skin inflammation, skin nodules
- inflammation of the vagina, breast discharge, breast enlargement, pelvic pain, benign breast lumps, uterine/vaginal bleeding (which usually subsides during continued treatment), genital discharge, hot flushes, painful periods, reduced periods, very heavy periods, vaginal dryness (causing difficult or painful sex), abnormal cervical smear, decreased interest in sex
- eye disorders, e.g., inflammation of the eyelid/pink eye or red eye, dry eyes
- candidiasis (fungal infection)
- anaemia (decrease in the number of red blood cells) which causes symptoms like easy fatigue and loss of energy, shortness of breath, headache and unusually rapid heart beat especially with exercise, difficulty concentrating, pale skin
- increase in the number of platelets in the blood which causes symptoms that are linked to blood clots and bleeding including weakness, bleeding, headache, dizziness, chest pain, and tingling in the hands and feet
- endocrine disorder (problem with the glands that secrete hormones internally into the blood stream). Hormones regulate several body functions like metabolism, growth and

development, tissue function, sexual function, reproduction, sleep, and mood, among other things in the body

- dull pain in the middle to upper right area of the abdomen, inflammation of the gallbladder (symptoms may include pain in the upper right abdomen, fever, nausea, yellowing of the skin and eyes (jaundice)
- aches and pains, e.g., back pain, limb pain, muscle cramps
- lack of energy, increased sweating, feeling generally unwell.

Frequency not known (cannot be estimated from available data):

- altered mood
- urticaria (nettle rash or hives - a raised, itchy rash that appears on the skin)
- intolerance to contact lenses.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of LEYLA**.**

5. How to store LEYLA

- Store all medicines out of reach of children
- Store at or below 25 °C
- Keep the blister in the outer carton until required for use
- Do not use after the expiry date stated on the carton or blister.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LEYLA contains

- **The active substances are:**
  - drospirenone and
  - ethinyl estradiol (as betadex clathrate).

  Each pink active film-coated tablet contains 3 mg drospirenone and0,020 mg ethinyl estradiol (as betadex clathrate).

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

- **The other ingredients are:**

Active film-coated tablets (pink)

- ***Tablet core***
  - Lactose monohydrate
  - Pregelatinised starch (maize)
  - Povidone K-30 (E1201)
  - Croscarmellose sodium
  - Polysorbate 80
  - Magnesium stearate (E572)

- ***Tablet film-coating***
  - Polyvinyl alcohol partial hydrolysed
  - Titanium dioxide (E171)
  - Macrogol 3350

- Talc
- Yellow iron oxide (E172)
- Red iron oxide (E172)
- Black iron oxide (E172).

Placebo film-coated tablets (white)

- ***Tablet core***
  - Lactose anhydrous
  - Povidone K-30 (E1201)
  - Magnesium stearate (E572)

- ***Tablet film-coating***
  - Polyvinyl alcohol partial hydrolysed
  - Titanium dioxide (E171)
  - Macrogol 3350
  - Talc.

What LEYLA looks like and contents of the pack

LEYLA tablets, both the active pink and the white placebo tablets, are film-coated tablets; the core of the tablet is coated.

The LEYLA active film coated tablet is pink, round with a 5,7 mm diameter.

The LEYLA inactive tablet is white, round with a 5,7 mm diameter.

LEYLA is supplied in a carton containing one blister strip with 28 tablets. Blister strip consists of clear to slightly opaque transparent PVC/PVDC and dull silver coloured aluminium foil. Each blister of LEYLA contains 24 pink, active film-coated tablets in the 1st, 2nd, 3rd and 4th rows of the strip and 4 white placebo (inactive) film coated tablets in row 4.

Pack sizes:

1 x 28 film-coated tablets

3 x 28 film-coated tablets

6 x 28 film-coated tablets

13 x 28 film-coated tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL: https://austell.co.za/product-info/

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