Package leaflet: Information for the user

Qlaira film-coated tablets
Estradiol valerate/Dienogest

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.

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”)

What is in this leaflet:

1. What Qlaira is and what it is used for

- Qlaira is a contraceptive pill and is used to prevent pregnancy.
- Qlaira is used for the treatment of heavy menstrual bleeding (not caused by any disease of the womb) in women who wish to use oral contraception.
- Each coloured, active tablet contains a small amount of female hormones, either estradiol valerate, or estradiol valerate combined with dienogest.
- The 2 white tablets contain no active substances and are called inactive tablets.
- Contraceptive pills that contain two hormones are called “combined pills”.

2. What you need to know before you take Qlaira

General notes

Before you start using Qlaira 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 Qlaira, 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 Qlaira, or where the reliability of Qlaira 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 Qlaira alters the monthly changes of body temperature and cervical mucus.

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

When not to take Qlaira

You should not use Qlaira 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.

Do not take Qlaira:

- 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) **liver disease** and your liver function is still not normal
- if you have (or have ever had) a **tumour of the liver**
- if you have (or have ever had) **cancer or suspected cancer of the breast or genital organs**
- if you have any **unexplained bleeding from the vagina**
- if you are **allergic** (hypersensitive) to estradiol valerate or dienogest, or any of the other ingredients of this medicine (listed in section 6). This may cause itching, rash or swelling.

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".

Tell your doctor if any of the following conditions apply to you.

In some situations you need to take special care while taking Qlaira or any other combined pill, and your doctor may need to examine you regularly. If the condition develops, or gets worse while you are using Qlaira, 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 gall bladder

- if you have jaundice
- 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 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 Qlaira;
- 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 Qlaira")
- if you have a disease that first appeared during pregnancy or earlier use of sex hormones, for example, hearing loss, porphyria (a disease of the blood), gestational herpes (skin rash with blisters during pregnancy), Sydenham's chorea (a nerve disease causing sudden movements of the body)
- if you have (or have ever had) golden brown pigment patches so-called "pregnancy patches" especially on the face (Chloasma). If this is the case, avoid direct exposure to sunlight or ultraviolet light
- if you have hereditary or acquired angioedema. Stop taking Qlaira and consult your doctor immediately if you experience symptoms such as swollen face, tongue and/or throat and/or difficulty swallowing or hives, together with difficulty breathing which are suggestive of an angioedema. Products containing oestrogens may induce or worsen symptoms of angioedema
- if you have cardiac or renal insufficiency.

Talk to your doctor before taking Qlaira.

Additional information on special populations

Use in children
Qlaira is not intended for use in females whose periods have not yet started.

BLOOD CLOTS

Using a combined hormonal contraceptive such as Qlaira 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 Qlaira 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; • 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;	Heart attack

Are you experiencing any of these signs?	What are you possibly suffering from?
• 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 Qlaira 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 Qlaira 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.
- The risk of a blood clot with Qlaira is about the same as with other combined hormonal contraceptives including contraceptives containing levonorgestrel.
- 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, norethisterone or norgestimate**	About 5-7 out of 10,000 women
Women using Qlaira	About the same as with other combined hormonal contraceptives including contraceptives containing levonorgestrel

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

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

- if you are very overweight (body mass index or BMI over 30 kg/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 Qlaira may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Qlaira 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 Qlaira needs to be stopped.

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

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

Qlaira and cancer

Breast cancer has been observed slightly more often in women using combined pills, but it is not known whether this is caused by the treatment itself. For example, it may be that more tumours are detected in women on combined pills because they are examined by their doctor more often. The risk 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 contraceptive pill users. In isolated cases, these tumours have led to life-threatening internal bleeding. Contact your doctor if you have unusually severe abdominal pain.

Some studies suggest that long-term use of the pill increases a woman's risk of developing **cervical cancer**. However, it is not clear to what extent sexual behaviour or other factors such as Human Papilloma Virus (HPV) increases this risk.

Psychiatric disorders:

Some women using hormonal contraceptives including Qlaira 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 of taking Qlaira, you may have unexpected bleeding. Usually bleeding starts on day 26, the day you take the second dark red tablet, or the following day(s). The information provided by women in the diaries they kept during a clinical study of Qlaira shows that it is not unusual to experience unexpected bleeding in a given cycle (10-18 % of users). If unexpected bleeding occurs more than 3 months in a row, or if it begins after some months, your doctor will have to investigate the cause.

What to do if no bleeding occurs on day 26 or the following day(s)

The information provided by women in the diaries they kept during a clinical study of Qlaira shows that it is not unusual to miss your regular bleeding after day 26 (observed in about 15 % of cycles).

If you have taken all the tablets correctly, have not had any 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 a row or you have taken the tablets incorrectly, you may be pregnant. Contact your doctor immediately. Do not start the next wallet until you are sure that you are not pregnant.

Other medicines and Qlaira

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 from whom you got the medicine) that you take Qlaira. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long.

Some medicines

- can have an influence on the blood levels of Qlaira

- can make it **less effective in preventing pregnancy**
- can cause unexpected bleeding.

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 infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efavirenz)
  - Hepatitis C virus (HCV) (such as combinations regimens ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin; glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir) may cause increases in liver function blood test results (increase in ALT liver enzyme) in women using CHCs containing ethinylestradiol. Qlaira contains estradiol instead of ethinylestradiol. It is not known whether an increase in ALT liver enzyme can occur when using Qlaira with this HCV combination regimen. Your doctor will advise you.
  - fungal infections (e.g. griseofulvin, ketoconazole)
- the herbal remedy St. John's wort

Qlaira may **influence the effect** of other medicines, e.g.

- medicines containing cyclosporin
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures).

Ask your doctor or pharmacist for advice before taking any medicine. Your doctor or pharmacist may advise on extra protective measures while you are taking other medication together with Qlaira.

Qlaira with food and drink

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

Laboratory tests

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

Pregnancy and breast-feeding

If you become pregnant while taking Qlaira, stop taking it immediately and contact your doctor. If you want to become pregnant, you can stop taking Qlaira at any time (see also “If you stop taking Qlaira”).

In general you should not take Qlaira while you are 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 when you are pregnant or breast-feeding.

Driving and using machines

There is nothing to suggest that the use of Qlaira affects driving or use of machines.

Qlaira contains lactose

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

3. How to take Qlaira

Each wallet contains 26 coloured active tablets and 2 white inactive tablets.

Take one tablet of Qlaira 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 at around the same time every day.

Preparation of the wallet

To help you keep track, there are 7 weekday sticker strips marked with the 7 days of the week.

Choose the weekday sticker strip that starts with the day you begin taking the tablets. For example, if you start on a Wednesday, use the weekday sticker strip that starts with “WED”.

Stick the weekday sticker strip along the top of the Qlaira wallet where it reads “Place weekday sticker strip here”, so that the first day is above the tablet marked “1”.

There is now a day shown above every tablet and you can see whether you have taken a pill on a particular day. Follow the direction of the arrow on the wallet until all 28 tablets have been taken.

Usually, so-called withdrawal bleeding starts when you are taking the second dark red tablet or the white tablets and may not have finished before you start the next wallet. Some women still experience bleeding after taking the first tablets of the new wallet.

Start the following wallet without a gap, in other words the day after you have finished your current wallet, even if the bleeding has not stopped. This means that you should start your following wallet on the same day of the week as the current wallet and that the withdrawal bleed should occur on the same weekdays each month.

If you use Qlaira in this manner, you are protected against pregnancy even during the 2 days when you take inactive tablets.

When can you start with the first wallet?

- *If you have not used a contraceptive with hormones during the previous month.*
  Start taking Qlaira on the first day of the cycle (that is, the first day of your period*).*
- *Changing from another combined hormonal contraceptive pill, or combined contraceptive vaginal ring or patch.*
  Start Qlaira the day after taking the last active tablet (the last tablet containing the active substances) of your previous pill. When changing from a combined contraceptive vaginal ring or patch, start using Qlaira on the day of removal or, follow the advice of your doctor.

- *Changing from a progestogen-only-method (progestogen-only pill, injection, implant or a progestogen-releasing 'IUS', intrauterine system).*
  You may switch from the progestogen-only pill any day (from an implant or the IUS 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) during the first **9 days** of Qlaira use.
- *After a miscarriage.*
  Follow the advice of your doctor.
- *After having a baby.*
  You can start Qlaira between **21 and 28 days** after having a baby. If you start later than **day 28**, use a barrier method (for example, a condom) during the first **9 days** of Qlaira use.

  If, after having a baby, you have had sex before re-starting Qlaira, be sure that you are not pregnant or wait until the next menstrual period.

  If you want to start Qlaira after having a baby and are breast-feeding, read the section on "Pregnancy and breast-feeding".

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

If you take more Qlaira than you should

There are no reports of serious harmful effects of taking too many Qlaira tablets.

If you take several active tablets at once, you may feel sick or throw up. Young girls may have bleeding from the vagina.

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

If you forget to take Qlaira

Inactive tablets: If you miss a white tablet (2 tablets at the end of the wallet), you do not need to take it later because they do not contain any active substances. However, it is important that you discard the missed white tablet(s) to make sure that the number of days when you take inactive tablets is not increased as this would increase the risk of pregnancy. Continue with the next tablet at the usual time.

Active tablets: Depending on the day of the cycle as indicated in the current wallet on which **one** active tablet has been missed, you may need to take **additional contraceptive precautions,** for example a barrier method such as a condom. **Take the tablets according to the following principles**. **See also the 'missed pill chart' for details.**

- If you are **less than 12 hours** late when taking a tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and then continue taking the tablets again at the usual time.

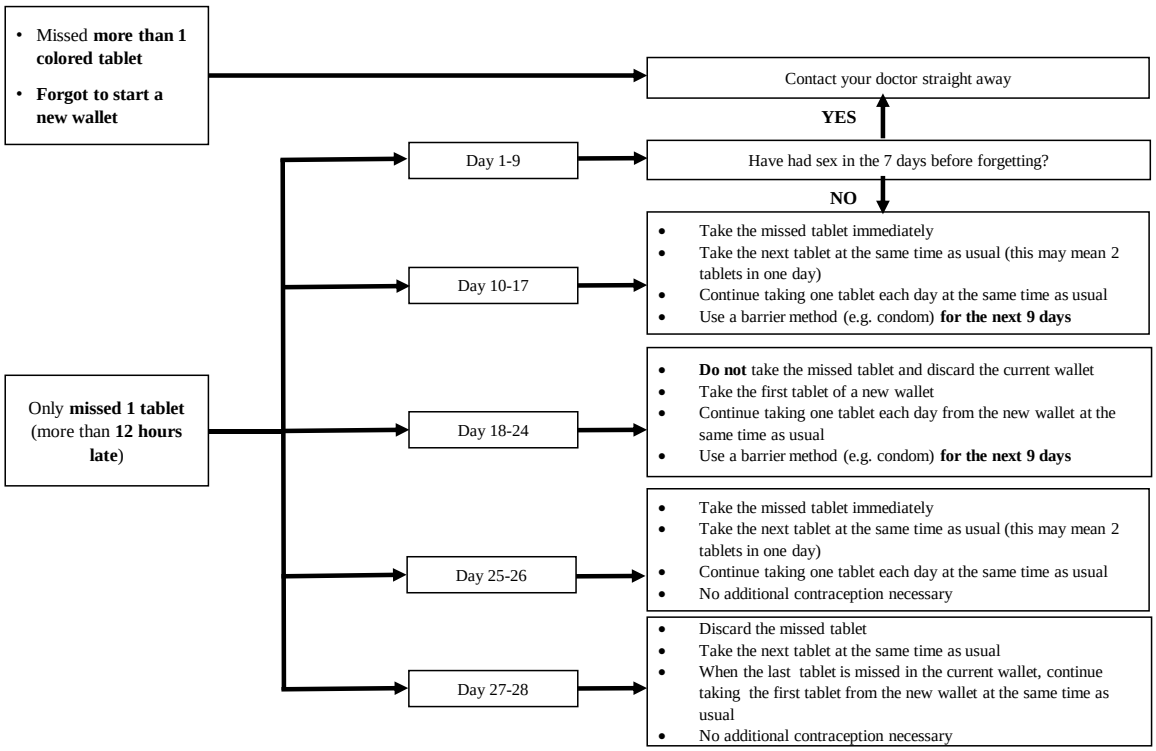
- If you are **more than 12 hours** late taking a tablet, the protection against pregnancy may be reduced. Depending on the day of the cycle as indicated in the current wallet on which one tablet has been missed, use additional contraceptive precautions e.g. a barrier method such as a condom. **See also the 'Missed pill chart' for details.**

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

Do not take more than 2 active tablets on a given day.

If you have forgotten to start a new wallet, or if you have missed one or more tablets during **days 3 - 9** of your wallet, there is a risk that you are already pregnant (if you had sex in the 7 days before forgetting the tablet). In that case, contact your doctor. The more tablets you have forgotten (especially those on **days 3 – 24**) and the closer they are to the inactive tablet phase, the greater the risk that the protection from pregnancy is reduced. **See also the 'missed pill chart' for details.**

If you have forgotten any of the active tablets in a wallet, and you have no bleeding at the end of a wallet, you may be pregnant. Contact your doctor before you start the next wallet.



Use in children

No data available in adolescents below 18 years.

What to do if you vomit or have severe diarrhoea

If you throw up within 3-4 hours of taking an active tablet or you have severe diarrhoea, there is a risk that the active substances in the pill are not fully absorbed by your body.

The situation is almost the same as forgetting a tablet. After throwing up or having diarrhoea, take the next tablet 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 Qlaira". If you do not want to change your normal tablet-taking pattern take the corresponding tablet from another wallet.

If you stop taking Qlaira

You can stop taking Qlaira at any time. 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 Qlaira and wait for a menstrual period before starting to try 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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Qlaira 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 Qlaira, please talk to your doctor.

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 Qlaira”.

Serious side effects

Serious reactions associated with the use of the pill, as well as the related symptoms, are described in the following sections: "Blood clots" and "Qlaira and cancer". Please read these sections carefully and consult your doctor at once where appropriate.

Other possible side effects

The following side effects have been linked with the use of Qlaira:

Common side effects (between 1 and 10 in every 100 users may be affected):
- headache
- abdominal pain, nausea
- acne
- no periods, breast discomfort, painful periods, irregular bleeding (heavy irregular bleeding)
- weight gain

Uncommon side effects (between 1 and 10 in every 1,000 users may be affected):
- fungal infections, fungal infection of the vulva and vagina, vaginal infection
- increased appetite
- depression, depressed mood, emotional disorder, problems sleeping, decreased interest in sex, mental disorder, mood swings
- dizziness, migraine
- hot flush, high blood pressure
- diarrhoea, vomiting
- increased liver enzymes
- hair loss, excessive sweating (hyperhidrosis), itching, rash
- muscle cramps

- swollen breasts, lumps in the breast, abnormal cell growth on the neck of the womb (cervical dysplasia), dysfunctional genital bleeding, pain with intercourse, fibrocystic breast disease, heavy periods, menstrual disorders, ovarian cyst, pelvic pain, premenstrual syndrome, growth in the uterus, contractions of the uterus, uterine/vaginal bleeding incl. spotting, vaginal discharge, vulvovaginal dryness
- fatigue, irritability, swelling of parts of your body, e.g. ankles (oedema)
- weight loss, blood pressure changes.

Rare side effects (between 1 and 10 in every 10,000 users may be affected):

- candida infection, oral herpes, pelvic inflammatory disease, a vessel disease of the eye resembling a fungal infection (presumed ocular histoplasmosis syndrome), a fungal infection of the skin (tinea versicolor), urinary tract infection, bacterial inflammation of the vagina
- fluid retention, increase in certain blood fats (triglycerides)
- aggression, anxiety, feelings of unhappiness, increased interest in sex, nervousness, nightmare, restlessness, problems sleeping, stress
- reduced attention, “pins and needles”, giddiness
- contact lens intolerance, dry eye, eye swelling
- heart attack (myocardial infarction), palpitations
- bleeding in a varicose vein, low blood pressure, inflammation of superficial veins, painful veins
- 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).
- constipation, dry mouth, indigestion, heartburn
- liver nodules (focal nodular hyperplasia), chronic inflammation of gallbladder
- allergic skin reactions, golden brown pigment patches (chloasma) and other pigmentation disorders, male pattern hair growth, excessive hair growth, skin conditions such as dermatitis and neurodermatitis, dandruff and oily skin (seborrhoea) and other skin disorders
- back pain, pain in jaw, sensation of heaviness
- urinary tract pain
- abnormal withdrawal bleeding, benign breast nodules, breast cancer in early stage, breast cysts, breast discharge, polyp on the neck of the womb, reddening on the neck of the womb, bleeding during intercourse, spontaneous milk flow, genital discharge, lighter periods, delayed periods, rupture of an ovarian cyst, vaginal odour, burning sensation in the vulva and vagina, vulvovaginal discomfort
- swollen lymph nodes
- asthma, difficulty in breathing, nose bleeding
- chest pain, tiredness and feeling generally unwell, fever
- abnormal smear from the neck of the womb

Further information (taken from the diaries women kept during a Qlaira clinical trial) on the possible side effects “irregular bleeding (heavy irregular bleeding)” and “no periods” is given in the sections “Bleeding between periods” and “What to do if no bleeding occurs on day 26 or the following day(s)”.

Description of selected adverse reactions

Adverse reactions with very low frequency or with delayed onset of symptoms which are considered to be related to the group of combined oral contraceptives, and could also occur during use of Qlaira, are listed below (see also sections “When not to take Qlaira”, “Warnings and precautions”:

- liver tumors (benign and malignant)
- Erythema nodosum (tender red nodules under the skin), Erythema multiforme (skin rash with red spots or lesions)
- hypersensitivity (including symptoms such as rash, urticaria)
- in women with hereditary angioedema (characterized by sudden swelling of e.g. the eyes, mouth, throat etc.) estrogens in combined oral contraceptive pills may induce or worsen symptoms of angioedema

In case of disturbed liver function, it may be necessary to temporarily stop the use of combined oral contraceptive pills.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Malta
ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Qlaira

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the wallet after 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 Qlaira contains

The active substances are estradiol valerate, or estradiol valerate combined with dienogest.

Each wallet (28 film-coated tablets) of Qlaira contains 26 active tablets in 4 different colours in rows 1, 2, 3 and 4, as well as 2 white inactive tablets in row 4.

Composition of the coloured tablets containing one or two active substances:

2 dark yellow tablets each containing 3 mg estradiol valerate
5 medium red tablets each containing 2 mg estradiol valerate and 2 mg dienogest
17 light yellow tablets each containing 2 mg estradiol valerate and 3 mg dienogest
2 dark red tablets each containing 1mg estradiol valerate

Composition of the white inactive tablets:

These tablets do not contain any active substances.

Other ingredients in the coloured active tablets are:

Tablet core: lactose monohydrate, maize starch, pregelatinised maize starch, povidone K25 (E1201), magnesium stearate (E572)

Tablet film-coating: hypromellose type 2910 (E464), macrogol 6000, talc (E553b), titanium dioxide (E171), iron oxide yellow (E172) and/or iron oxide red (E172)

Other ingredients in the white inactive tablets are:

Tablet core: lactose monohydrate, maize starch, povidone K25 (E1201), magnesium stearate (E572)

Tablet film-coating: hypromellose type 2910 (E464), talc (E553b), titanium dioxide (E171)

What Qlaira looks like and content of the pack

Qlaira tablets are film-coated tablets; the core of the tablet is covered with a coating.

Each wallet (28 film-coated tablets) contains 2 dark yellow tablets in row 1, 5 medium red tablets in row 1, 17 light yellow tablets in rows 2, 3 and 4, 2 dark red tablets in row 4 as well as 2 white tablets in row 4.

The dark yellow active tablet is round with biconvex faces, one side is marked with the letters “DD” in a regular hexagon.

The medium red active tablet is round with biconvex faces, one side is marked with the letters “DJ” in a regular hexagon.

The light yellow active tablet is round with biconvex faces, one side is marked with the letters “DH” in a regular hexagon.

The dark red active tablet is round with biconvex faces, one side is marked with the letters “DN” in a regular hexagon.

The white inactive tablet is round with biconvex faces, one side is marked with the letters “DT” in a regular hexagon.

Qlaira is available in packs of 1, 3, or 6 wallets each containing 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Bayer Limited, 1st Floor, The Grange Offices, The Grange, Brewery Road, Stillorgan, Co. Dublin, A94 H2K7, Ireland.

Manufacturer

Bayer Weimar GmbH und Co. KG
99427 Weimar
Germany

and

Bayer AG
13342 Berlin
Germany

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

- Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden: **QLAIRA/Qlaira**

- Italy: **KLAIRA**

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