

Package leaflet Qlaira 1 of 20  
Information for the user

## PACKAGE LEAFLET: INFORMATION FOR THE USER

Qlaira film-coated tablets  
estradiol valerate/dienogest

Read the entire leaflet carefully before you start using this medicine because it contains important information for you. Keep this leaflet. You may need to read it again.

- Do you have any questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may be harmful to others.
- Do you experience a lot of side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Please contact your doctor or pharmacist. Important things you need to know about combined hormonal contraceptives:
- Do you experience a lot of discomfort from any of the side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Please contact your doctor or pharmacist.

Important things you need to know about combined hormonal contraceptives:

- These agents are among the most reliable reversible contraceptive methods, provided used correctly
- They carry a slightly higher risk of developing a blood clot (thrombosis) in the veins and arteries, especially in the first year you use a combined hormonal contraceptive or if you start using a combined hormonal contraceptive again after a break of 4 weeks or longer - Pay close attention and contact your doctor if you think you may have symptoms of a blood clot (see section 2 'Blood clots (thrombosis)'). Contents of this leaflet:

1. WHAT IS QLAIRA AND WHAT IS THIS MEDICINE USED FOR?
2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR MUST YOU BE EXTRA CAUTIOUS WITH IT?

When should you not use this medicine?

When should you be extra cautious with this medicine?

Blood clots (thrombosis)

This medicine and cancer

Mental disorders

Intermenstrual bleeding

What to do if you do not have bleeding on day 26 or on (one of) the following

What to do if you do not get bleeding on day 26 or on (one of) the following day(and)

Are you using any other medications?

What should you pay attention to with food and drink?

Laboratory tests

Pregnancy and breastfeeding

Driving ability and the use of machines

Qlaira contains lactose

### 3. HOW DO YOU USE THIS MEDICINE?

Preparation of the wallet

When can you start with the first wallet?

Have you taken too much of this medicine?

Did you forget to take this medicine?

Use in children

What to do in case of vomiting or severe diarrhea

If you stop using this medicine

### 4. POSSIBLE SIDE EFFECTS

### 5. HOW DO YOU STORE THIS MEDICINE?

### 6. CONTENTS OF THE PACKAGE AND OTHER INFORMATION

#### 1. WHAT IS QLAIRA AND WHAT IS THIS MEDICINE 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 a condition of the uterus) in women who wish to use oral contraception.
- Each colored, active tablet contains a small amount of female hormones, namely estradiol valerate or estradiol valerate with dienogest.
- The two white tablets contain no active ingredients and are also called inactive tablets.
- Contraceptive pills that contain two hormones are called 'combination pills'.

#### 2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR SHOULD YOU BE EXTRA CAREFUL WITH IT?

##### General remarks

Read before you start using Qlaira the information about blood clots (thrombosis) in section 2. It is especially important that you read what the symptoms of a blood clot are – see section 2 'Blood clots (thrombosis)'.

Before you can start using this medicine, your doctor will ask you some questions about your personal medical history and that of your close family members. The doctor will also measure your blood pressure and, depending on your personal situation, may also perform other tests.

This leaflet describes various situations in which you must stop using this medicine or in which its reliability may be reduced. In these situations, you must either abstain from intercourse, or use an additional non-hormonal contraceptive, such as a condom or another barrier method. Do not use the temperature method or periodic abstinence. These methods can be unreliable because this medicine affects the monthly changes in body temperature and cervical mucus. Like other hormonal contraceptives, this medicine does not protect against infection with the HIV virus (AIDS) or other sexually transmitted diseases (STDs).

When should you not use this medicine? with the HIV virus (AIDS) or other sexually transmitted infections (STIs).

When should you not use this medicine?

You must not use this medicine if you have any of the conditions listed below. If you have one or more of the conditions listed below, tell your doctor. Your doctor will discuss with you which other form of contraception is more suitable for you.

Do not use this medicine:

- if you have a blood clot in a blood vessel of the legs (deep vein thrombosis, DVT), the lungs (pulmonary embolism, PE) or another organ, or have had this in the past
- if you know you have a disorder that affects your blood clotting – for example, protein C deficiency, protein S deficiency, antithrombin III deficiency, factor V Leiden or antibodies against phospholipids
- if you need to undergo surgery or you are unable to walk for a long period (see section 'Blood clots (thrombosis)')
- if you have ever had a heart attack or stroke
- if you have ever had a heart attack or stroke
- you have angina pectoris (a condition causing severe chest pain and can be a first sign of a heart attack) or a transient ischemic attack (TIA – transient symptoms of a stroke), or have ever had this ischemic attack (TIA – transient symptoms of a stroke), or has ever had this
- you have any of the following diseases, which can increase the risk of a blood clot in your arteries: severe diabetes (diabetes mellitus) with blood vessel damage  
severely increased  
serious elevated blood pressure  
a severely increased fat levels in your blood (cholesterol or triglycerides)  
a condition called hyperhomocysteinemia
- if you have or have had a type of migraine called 'migraine with aura'
- if you have a liver disorder and your liver function is not yet normal (or have had this in the past)
- if you have a liver tumor (or have had this in the past)
- if you have breast cancer or cancer of the genital organs (or have had this in the past), or if it is suspected that you have it
- if you have unexplained vaginal bleeding
- if you are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6. This can cause itching, rash, or swelling.

When should you be extra careful with this medicine?

When should you contact your doctor?

Seek emergency medical help

- if you notice possible complaints or symptoms of a blood clot, which may mean that you have a blood clot in your leg (i.e., deep vein thrombosis), a blood clot in your lung (i.e., pulmonary embolism), a heart attack or a stroke (see below the section 'Blood clots (thrombosis)').

For a description of the complaints or symptoms of these serious side effects, go to 'How to recognize a blood clot?'

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

In some situations, you need to be extra careful when using this medicine or another contraceptive with two hormones. It may be necessary for you to be regularly monitored by your doctor. If the condition occurs or worsens while you are Qlaira using it, you should also inform your doctor. If someone in your immediate family has or has had breast cancer

- If someone in your immediate family has or has had breast cancer
- If you have a liver or gallbladder condition
- If you jaundice have
- If you have diabetes (diabetes mellitus) have If you have depression (severe despondency)
- If you have Crohn's disease
- Crohn's or ulcerative colitis (chronic inflammatory bowel disease) If you have systemic lupus erythematosus (SLE – a disease that affects your natural immune system affects) have If you have hemolytic-uremic causes) have caused) has
- If you have sickle cell anemia (a hereditary disease of the red blood cells)
- If you have elevated fat levels in your blood (hypertriglyceridemia) or this condition runs in your family or has occurred in your family. Hypertriglyceridemia has been associated with an increased risk of developing pancreatitis (an inflammation of the pancreas)
- If you need to undergo surgery or are immobilized for a long time (see 'Blood clots (thrombosis)' in section 2)
- If you have recently given birth, you have an increased risk of developing blood clots. Ask your doctor how soon after delivery you can start using Qlaira
- If you have an inflammation of the veins just under the skin (superficial thrombophlebitis)
- If you have varicose veins If you have epilepsy (see 'Are you taking any other medicines?')
- If you have a condition that first occurred during pregnancy or earlier
- use of use of sex hormones, for example hearing loss, porphyria (a blood disorder), herpes gestationis (skin rash with blisters during pregnancy), chorea of Sydenham (disorder of the nerves causing sudden movements of the body)
- If you have chloasma (yellow-brown pigment spots, so-called 'pregnancy spots', especially on the face) or have ever had it. If this is the case, it is advisable to avoid direct exposure to sunlight or ultraviolet light.
- If you have hereditary and acquired angioedema. Stop taking Qlaira and consult your doctor immediately if you notice any of the following symptoms, such as swelling of the face, tongue and/or throat, and/or difficulty swallowing, or a skin rash with pink bumps and severe itching (hives or welts), along with difficulty breathing; these symptoms indicate angioedema. Products containing estrogenic hormones can trigger or worsen the symptoms of angioedema.
- If your heart or kidneys are not functioning properly (heart or kidney failure)

Contact your doctor or pharmacist before using this medicine.

Additional information on special populations

Use in children

Qlaira is not intended for women who have not yet started menstruating.

**BLOOD CLOTS (THROMBOSIS)**

If you use a combined hormonal contraceptive like Qlaira, you have a higher risk of developing blood clots than if you do not use a combined hormonal contraceptive. In rare cases, a blood clot can block a blood vessel and cause serious problems.

Blood clots can occur

- in veins (this is called 'venous thrombosis', 'venous thromboembolism', or VTE),
- in arteries (this is called 'arterial thrombosis', 'arterial thromboembolism', or ATE).

One does not always fully recover from blood clots. In rare cases, there can be long-term serious effects, or in very rare cases, blood clots can be fatal.

It is important to know that the overall risk of a harmful blood clot from Qlaira is small.

### HOW TO RECOGNIZE A BLOOD CLOT?

Seek emergency medical help if you notice any of the following complaints or symptoms.

Do you experience any of these complaints or symptoms?	What might you suffer from?
<ul style="list-style-type: none"> <li>• swelling of a leg or along a vein in a leg or foot, especially if accompanied by:                             <ul style="list-style-type: none"> <li>• pain or tenderness in the leg, which you may only feel when standing or walking</li> <li>• increased temperature in the affected leg</li> <li>• discoloration of the skin of the leg, for example pale, turning red or blue</li> </ul> </li> </ul>	Deep vein thrombosis
<ul style="list-style-type: none"> <li>• sudden unexplained shortness of breath or rapid breathing</li> <li>• sudden coughing without an obvious cause, where you may cough up blood</li> <li>• sharp chest pain, which may worsen when you breathe deeply</li> <li>• severe lightheadedness or dizziness</li> <li>• rapid or irregular heartbeat</li> <li>• severe pain in your stomach.</li> </ul> <p>If in doubt, contact a doctor, as some of these symptoms, such as coughing or shortness of breath, may be mistakenly attributed to a milder condition, such as a respiratory infection (e.g., cold).</p>	Pulmonary embolism
Symptoms usually occur in one eye: <ul style="list-style-type: none"> <li>• sudden loss of vision, or</li> <li>• painless blurred vision, which can develop into loss of the vision</li> </ul>	Venous thrombosis in the retina (blood clot in the eye)

<ul style="list-style-type: none"> <li>• pain, discomfort, pressure or heaviness in the chest</li> <li>• tightness or fullness in the chest, arm or below the breastbone</li> <li>• feeling of fullness, indigestion or gasping for breath</li> <li>• discomfort in the upper body radiating to the back, jaw, throat, arm and stomach</li> <li>• sweating, nausea, vomiting or dizziness</li> <li>• extreme weakness, anxiety or shortness of breath</li> <li>• rapid or irregular heartbeat</li> </ul>	<p>Heart attack</p>
<ul style="list-style-type: none"> <li>• sudden weakness or numbness of the face, arm, or leg, especially on one side of the body</li> <li>• sudden confusion, difficulty speaking or understanding</li> <li>• sudden difficulty seeing in one or both eyes</li> <li>• sudden difficulty walking, dizziness, loss of balance or coordination</li> <li>• sudden, severe, or prolonged headache without known cause</li> <li>• reduced consciousness or fainting with or without epileptic attack.</li> </ul> <p>The symptoms of a stroke can sometimes be brief and recover almost immediately and completely. However, you must still emergency seek medical assistance, because you may have a chance walk to have another stroke.</p>	<p>Stroke</p>
<ul style="list-style-type: none"> <li>• swelling and slight bluish discoloration of an arm or leg</li> <li>• severe pain in your abdomen (acute abdomen)</li> </ul>	<p>Blood clots that block other blood vessels block</p>

### BLOOD CLOTS IN A VEIN

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

- The use of combined hormonal contraceptives has been associated with a higher risk of blood clots in a vein (venous thrombosis). However, these side effects are rare occurrences. They usually occur in the first year that a combined hormonal contraceptive is used.

- If a blood clot forms in a vein in a leg or foot, it can cause a deep vein thrombosis (DVT).
- If a blood clot is carried from the leg and reaches the lung, it can cause a pulmonary embolism.
- It is very rare for a blood clot to form in a vein in another organ, such as the eye (retinal vein thrombosis).

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

The risk of a blood clot in a vein is highest in the first year that a woman first a combined hormonal contraceptive. The risk may also be increased if you start using a combined hormonal contraceptive (the same product, or a different product than before) again after a break of 4 weeks or longer. After the first year, the risk decreases, but it remains slightly higher than if you do not use a combined

hormonal contraceptive. If you stop using

Qlaira Qlaira How high is the risk of a blood clot?

The risk depends on your natural risk of VTE, and on the type of combined hormonal contraceptive you use. The overall risk of a blood clot in a leg or lung (deep vein thrombosis or pulmonary embolism)

The overall risk of a blood clot in a leg or lung (deep vein thrombosis or pulmonary embolism) Qlaira is small. is small.

and are not pregnant, about 2 will develop a blood clot in a year. blood clot.

- Of every 10,000 women using a combined hormonal contraceptive that levonorgestrel, norethisterone or norgestimate contains, approximately 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 combined hormonal contraceptives that levonorgestrel contain.
- The risk of developing a blood clot depends on your personal medical history (see sections 'Factors that increase your risk of a blood clot in a vein/artery' below).

	Risk of developing a blood clot in a year
Women who do not use a combined hormonal pill use and are not pregnant	About 2 out of every 10,000 women
Women who use a combination pill that levonorgestrel, norethisterone or norgestimate contains	About 5-7 out of every 10,000 women
Women who Qlaira use	About the same as with other combined hormonal contraceptives including combined hormonal contraceptives that levonorgestrel contain

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

The risk of a blood clot with Qlaira is small, but there are certain conditions that increase the risk increase. Your risk is higher:

- if you are severely overweight (BMI [body mass index] higher than 30 kg/m<sup>2</sup>)
- if one of your close relatives had a blood clot at a young age (e.g., before the age of 50) in a leg, lung, or other organ. In that case, you may have an inherited clotting disorder .
- if you need to undergo surgery, or if you are immobile for a long time due to an injury or disease, or if your leg is in a cast. It may be necessary to stop using it before surgery, or when you are less mobile, for a few weeks. Qlaira. If you need to stop using Qlaira, ask your doctor when you can start using it again.
- as you get older (particularly over the age of 35)
- if you have given birth in the past few weeks.

The risk of a blood clot increases as more of these conditions apply to you. A flight (longer than 4 hours) can temporarily increase your risk of a blood clot, especially

if some of the other mentioned conditions apply to you. It is important that you tell your doctor if one or more of these conditions apply to you, even if you are unsure. Your doctor may decide that you need to stop using

Qlaira apply, even if you have doubts about this. Your doctor may decide that you should stop using If any of the above-mentioned conditions change while you are using Qlaira.

If one of the above-mentioned conditions changes while you Qlaira used, for example if a close relative has a blood clot (thrombosis) without a known cause, or if you gain a lot of weight, tell your doctor.

### BLOOD CLOT IN AN ARTERY

What can happen if a blood clot forms in an artery?

Just like a blood clot in a vein, a blood clot in an artery can cause serious problems. It can, for example, cause a heart attack or a stroke.

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

It is important that you know that the risk of a heart attack or stroke from using Qlaira is very small, but can increase:

- with increasing age (above about 35 years)
- if you smoke. If you use a combined hormonal contraceptive like Qlaira , it is recommended that you stop smoking. If you cannot stop smoking and are over 35 years old, 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 had a heart attack or

stroke at a young age (before the age of 50) has had. In that case, you may also have an increased risk of a heart attack or stroke.

- if you, or an immediate family member, have high levels of fat in the blood (cholesterol or triglycerides)
- if you suffer from migraines, especially migraines with aura
- if you have a heart condition (heart valve disorder, or a heart rhythm disorder called atrial fibrillation)
- if you have diabetes.

If more than one of these conditions applies to you, or if one of these conditions is particularly severe, the risk of developing a blood clot may be even further increased.

If any of the above conditions change while you are using Qlaira, for example, if you start smoking or if an immediate family member develops a blood clot (thrombosis) without a known cause, or if you gain a lot of weight, inform your doctor.

#### This medicine and cancer

In women using a combination pill, breast cancer is detected slightly more often, but it is not known if this is caused by the use of the pill. It may also be that more breast cancer is detected in women using a combination pill because they are examined by their doctor more frequently. The risk of breast cancer gradually decreases after stopping the combination pill. It is important to regularly check your breasts. If you feel a lump, you should contact your doctor.

In rare cases, benign liver tumors have been found in pill users and in even rarer cases malignant liver tumors. In isolated cases, these tumors have led to a life-threatening internal bleeding. Contact your doctor if you experience 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 yet clear to what extent sexual behavior, or other factors such as the human papillomavirus (HPV) increase this risk.

#### Psychiatric disorders

Some women using hormonal contraceptives including Qlaira have reported depression or low mood. Depression can be severe and may sometimes lead to suicidal thoughts. If you experience mood changes and symptoms of depression, contact your doctor as soon as possible for further medical advice. Intermenstrual bleeding

During the first few months of using this medication, you may experience unexpected bleeding. During the first few months of using this medication, you may experience unexpected bleeding. Usually, bleeding starts on day 26, the day you take the second dark red tablet, or on (one of) the following day(s). of the following day(s).

From information in diaries that women kept during a clinical study with this medicine, it appears that it is not uncommon to experience unexpected bleeding in a certain pill cycle (in 10-18% of users). If unexpected bleeding continues for more than 3 consecutive months, or if it starts after a few months, your doctor should investigate the cause. What to do if you do not get bleeding on day 26 or on (one of) the following day(s)

From information in diaries that women kept during a clinical study with this medicine, it appears that it is not uncommon for you not to get bleeding after day 26 (observed in 15% of pill cycles). If you have taken all the tablets correctly, if you have not vomited, not had severe

diarrhea, and if you have not used other medications, it is highly unlikely that you are pregnant. If the expected bleeding does not occur twice in a row, or if you have not taken the tablets correctly,

you may be pregnant. Contact your doctor immediately. Do not start the next wallet until you are sure that you are not pregnant. Are you using any other medications?

Always tell the doctor who prescribes this medicine to you which medications and herbal remedies you are already using.

Also tell any other doctor or dentist who prescribes you another medicine (or the pharmacist from whom you are getting it) the medicine receives) that you are using this medicine. They can tell you if it is necessary to take extra contraceptive measures (e.g., condoms) and, if so, how long you need to do this. Some medicines

- can affect the blood levels of
- Qlaira - can reduce the protection against pregnancy
- can cause unexpected bleeding.

These include:

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medicines for the treatment of: - epilepsy (e.g., primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate))

- tuberculosis (for example rifampicin)
- infections with the HIV and hepatitis C virus (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efavirenz)
- the hepatitis C virus (HCV) combination treatments ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin; glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir can cause an increase in a liver enzyme (ALT, a liver function blood test) in women using combined hormonal contraceptives with ethinylestradiol. Qlaira contains estradiol instead of ethinylestradiol. It is not known if an increase in the ALT liver enzyme can also occur when Qlaira is used with this HCV combination treatment. Your doctor will advise you.

- fungal infections (for example griseofulvin, ketoconazole)
- o the herbal remedy St. John's wort.

- Qlaira can affect the action of other medicines, for example
  - o medicines containing cyclosporine
  - o the anti-epileptic drug lamotrigine (this can lead to more frequent seizures).

Ask your doctor or pharmacist for advice before taking any medicine. Your doctor or pharmacist can advise you on additional protective measures for the period during which you are using Qlaira in addition to another medicine.

What should you pay attention to with food and drink?

This medicine can be taken with or without food, if necessary with a little water.

Laboratory tests

If you need to have blood tests or other laboratory tests, tell your doctor or the laboratory staff that you are using the pill. Contraceptive pills can affect the results of some tests.

Pregnancy and breastfeeding

If you become pregnant while using this medicine, you should stop immediately and contact your doctor. If you want to become pregnant, you can stop using this medicine whenever you want (see 'If you stop using this medicine').

In general, you should not use this medicine if you are breastfeeding. If you want to use the pill while breastfeeding, you should contact your doctor.

If you are pregnant or breastfeeding, ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

There is no information to suggest that this medicine affects driving or the use of machines.

Qlaira contains lactose

If your doctor has told you that you have an intolerance to some sugars, contact your doctor before using this medicine.

### 3. HOW TO USE THIS MEDICINE?

Each wallet contains 26 colored, active tablets and 2 white, inactive tablets.

Take 1 tablet every day, if necessary with a little water. You may take the tablets with or without food but you must take the tablets at around the same time every day.

Preparation of the wallet

To be able to monitor the daily intake of the pill, you receive 7 week stickers with the 7 days of the week on them.

Choose the week sticker that starts with the day you begin taking the tablets. For example: if you start on Wednesday, use the week sticker that starts with 'Wed'.

Place the week sticker at the top of the Qlairawallet where it says 'Place the week sticker here' so that the first day is above the tablet marked '1'.

Now each tablet has a day indicated above it. This allows you to check if you have taken a pill on a certain day. Follow the direction of the arrow on the wallet until all 28 tablets are taken.

You usually get a so-called withdrawal bleed on the days you use the second dark red or the white tablets. It may be that this is not over yet when you start the next wallet. begins. Some women still experience bleeding after taking the first tablets of the new wallet.

Start without a break with the next wallet. In other words: on the day after you have taken the last tablet from your current wallet; even if your bleeding has not yet stopped. This means that you must start the next wallet on the same day of the week as your current wallet and that the withdrawal bleeding will occur on the same days of the week each month.

If you use this medicine in this way, you are also protected against pregnancy during the 2 days that you use a non-active tablet.

When can you start with the first wallet?

- If you have not used a hormonal contraceptive in the past month.

Start this medicine on the first day of the cycle (this is the first day of your period).

- Switching from another combination pill, or combined vaginal ring or contraceptive patch. Start this medicine on the day after you have taken the last active tablet (the last tablet with active ingredients) of your previous pill. Start, if you are switching from a combined vaginal contraceptive ring or contraceptive patch, on the day of removal, or follow your doctor's advice.
- Switching from a progestogen-only contraceptive method (progestogen-only contraceptive pill (also called 'mini-pill'), injection, implant or a progestogen-releasing IUD). You may switch from a progestogen-only contraceptive pill on any desired day (for an implant or IUD on the day it is removed; for the injection on the day you should receive the next injection) but in all cases, you must use an additional contraceptive method (e.g., a condom) for the first 9 days of pill use.
- After a miscarriage or abortion.

Follow your doctor's advice.

- After childbirth.

If you have given birth, you can start this medication 21 to 28 days after delivery. If you start after day 28,

you must use a so-called barrier method (e.g., a condom) for the first 9 days of using this medication. If you have had intercourse after childbirth before starting this medication, it must first be certain that you are not pregnant or you must wait until your next period. Read the section 'Pregnancy and breastfeeding' if you want to start this medication after childbirth and are still breastfeeding.

drug and is still breastfeeding.

Ask your doctor what to do if you are unsure when you can start.

Have you taken too much of this medicine?

There have been no reports of serious harmful effects from taking too much Qlaira- tablets.

If you have taken multiple tablets at once, you may experience nausea or vomiting. In young girls, vaginal bleeding may occur.

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

Have you forgotten to take this medicine?

**Non-active tablets:** If you forget a white tablet (2 tablets at the end of the wallet), you do not need to take it later, as they contain no active ingredients. However, it is important that you discard the forgotten white tablet(s) so that the number of days you take non-active tablets does not increase, which would increase the chance 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 you forget one active tablet, you may need to take extra contraceptive measures, such as a barrier method like a condom. Take the tablets according to the following rules. See also the 'missed pill chart' for more information.

- If you are less than 12 hours late in taking a tablet, the protection against pregnancy is not reduced. Take that tablet as soon as you remember and take the next tablets at the usual time again.
- 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 you forget one tablet, you must take extra contraceptive measures, such as a barrier method like a condom. See also the 'forgotten-pill-schedule' for more information.
- More than 1 active tablet forgotten in this wallet

Contact your doctor.

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

If you forgot to start a new wallet, or if you forgot one or more tablets during days 3-9 of your wallet, there is a chance you are already pregnant (if you had intercourse in the 7 days before forgetting the pill). In that case, contact your doctor. The more tablets you

have forgotten (especially those from days 3-24) and the closer these tablets are to the non-active tablets, the greater the chance that the protection against pregnancy is reduced. See also the 'forgotten-pill-schedule' for more information. If you forgot one of the active tablets in a wallet and you do not get a bleeding at the end of the wallet, you may be pregnant. Then contact your doctor before starting the next

wallet. Did you forget to take this medicine? More than 1 colored (active) tablet

Did you forget to take this medicine?

More than 1 colored (active) tablet forgotten / Forgot to start with a new wallet. Contact your doctor immediately.

Only 1 active tablet forgotten (more than 12 hours late taken)

Day 1–9

If you have had intercourse in the 7 days before the forgotten intercourse, contact your doctor.

If you have not had intercourse in the 7 days before the forgotten:

- Take the forgotten tablet immediately.
- Take the next tablet at the usual time (this may mean taking 2 tablets in 1 day).
- Continue taking 1 tablet every day at the usual time.
- Use a barrier method (e.g., a condom) for the next 9 days.

Day 10–17

- Take the forgotten tablet immediately.
- Take the next tablet at the usual time (this may mean taking 2 tablets in 1 day).
- Continue taking 1 tablet every day at the usual time.
- Use a barrier method (e.g., a condom) for the next 9 days.

Day 18–24

- Do not take the missed tablet.
- Discard the current wallet.
- Start immediately with a new wallet.
- Continue taking 1 tablet every day at the usual time.
- Use a barrier method (e.g., a condom) for the next 9 days.

Day 25–26

- Take the missed tablet immediately.
- Take the next tablet at the usual time (this may mean taking 2 tablets in 1 day).
- Then continue taking 1 tablet every day at the usual time.
- You do not need to use additional contraception.

Day 27–28 (white, inactive tablets)

- Discard the missed tablet.
- Take the next tablet at the usual time.
- If the last tablet in the wallet is missed, start the first tablet from a new wallet at the usual time.
- You do not need to use additional contraception.

If you do not have a withdrawal bleed at the end of the wallet after missing an active tablet, you may be pregnant. In that case, contact your doctor before starting a new wallet.

Use in children

No data are available for adolescents under 18 years.

## What to do in case of vomiting or severe diarrhea

If you vomit or have severe diarrhea within 3-4 hours after taking an active tablet, there is a chance that the active ingredients of the pill are not fully absorbed by your body. This situation is similar to forgetting a tablet. After vomiting or diarrhea, you should take the next tablet as soon as possible. If possible, you should take it within 12 hours of the time you normally take your pill. If this is not possible, or if the 12 hours have already passed, you should follow the advice given under 'Have you forgotten to take this medicine?'. If you do not want to change your normal pill-taking schedule, you should take the same tablet from another wallet. If you stop using this medicine

## You can stop using

Qlaira Qlairayou can ask your doctor for advice on other reliable contraceptives. If you want to become pregnant, stop using this medicine and wait until you have a period before you start trying to conceive. You can then more easily calculate the expected due date. Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS Like any medicine,

### 4. POSSIBLE SIDE EFFECTS

Like any medicine can Qlaira may cause side effects, although not everyone will experience them. If you experience a side effect, especially if it is severe and persistent, or if there is a change in your health condition that you think may be caused by Qlaira, please contact your doctor.

All women using combined hormonal contraceptives have a higher risk of blood clots in the veins (venous thromboembolism [VTE]) or blood clots in the arteries (arterial thromboembolism [ATE]). For more information on the different risks of using combined hormonal contraceptives, see section 2 'When should you not use this medicine or should you be extra careful?'. Serious side effects

Serious side effects associated with the use of the pill, as well as the associated symptoms, are described in the sections 'Blood clots (thrombosis)' and 'This medicine and cancer'. Please read these sections carefully and consult your doctor if necessary. Other possible side effects

The following side effects have been associated with the use of this medicine:

Common side effects (occur in less than 1 in 10 users):

- headache
- headache
- abdominal pain, nausea
- acne
- absence of bleeding, painful breasts, painful bleeding, irregular bleeding (heavy, irregular bleeding)
- weight gain.

Sometimes occurring side effects (occur in less than 1 in 100 users):

- fungal infections, fungal infection of the vulva (the external genitalia) and the vagina, vaginal infection

- increased appetite
- depression, depressed mood, emotional disorder, sleep problems, decreased libido, psychological disorder, mood swings
- dizziness, migraine
- hot flashes, high blood pressure
- diarrhea, vomiting
- elevated liver enzymes
- hair loss, excessive sweating (hyperhidrosis), itching, rash
- muscle cramps
- enlargement of the breasts, lumps in the breast, abnormal cell growth in the cervix (cervical dysplasia), non-functional bleeding from the genital organs, pain during intercourse, so-called fibrocystic lumps in the breast, severe withdrawal bleeding, bleeding disorders, cysts (cavities with liquid content) in the ovaries, pain in the pelvis, PMS (premenstrual syndrome), (wild) growth of tissue in the uterus (e.g. fibroids), contractions of the uterus, vaginal bleeding whether or not in drips, vaginal discharge, dryness of labia and vagina
- fatigue, irritability, swelling in a part of the body, for example the ankles (edema)
- weight loss, changes in blood pressure.

Rare side effects (occur in less than 1 in 1000 users):

- candida yeast infection, oral herpes ('cold sores' on the lips), inflammation in the small pelvis, condition of a blood vessel in the eye resembling a fungal infection (presumed ocular histoplasmosis syndrome), fungal infection of the skin (tinea versicolor), urinary tract infection, bacterial infection in the vagina
- fluid retention, increase in certain blood fats (triglycerides)
- aggression, anxiety, feeling unhappy, increased sex drive, nervousness, nightmares, restlessness, sleep problems, stress
- decreased attention, feeling of being pricked by pins and needles, light-headedness - intolerance to contact lenses, dry eyes, swollen eyes
- 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:
  - harmful blood clots in a vein or artery, for example:
    - o in a leg or foot (i.e. deep vein thrombosis) in a leg or foot (i.e., deep vein thrombosis)
    - o in a lung (i.e. pulmonary embolism) in a lung (i.e., pulmonary embolism)
    - o heart attack
    - o stroke
    - o 'mini-stroke' or temporary symptoms similar to a stroke, known as TIA (transient ischemic attack)
    - o blood clots in the liver, stomach/intestines, kidneys, or eyes

The risk of developing a blood clot is higher if there are other conditions that apply to you that increase this risk (see section 2 for more information on the

conditions that increase the risk of blood clots and the symptoms of a blood clot that increase the risk of blood clots and the symptoms of a

- constipation, dry mouth, indigestion, heartburn- nodules in the liver (focal nodular hyperplasia), chronic inflammation of the gallbladder
- allergic skin reaction, yellow-brown pigment spots on the skin (chloasma) and others
- nodules in the liver (focal nodular hyperplasia), chronic inflammation of the gallbladder

- allergic skin reaction, yellow-brown pigment spots on the skin (chloasma) and others pigmentation disorders, male pattern hair growth, excessive hair growth, skin conditions such as skin inflammation and neurodermatitis (skin conditions associated with itching on which the nervous system has an influence), dandruff and oily skin (seborrhea) and other skin conditions
- back pain, jaw pain, feeling of heaviness
- urinary tract pain
- abnormal withdrawal bleeding, benign breast lumps, early-stage breast cancer, cysts (cavities/blisters with liquid content) in the breast, breast discharge, polyps in the cervix, redness of the cervix, bleeding during intercourse, spontaneous milk discharge, genital discharge, lighter bleeding, late occurrence of withdrawal bleeding, rupture of an ovarian cyst, strong vaginal odor, burning sensation of the labia and in the vagina, uncomfortable feeling in labia or vagina - swollen lymph nodes
- asthma, difficulty breathing, nosebleed
- chest pain, fatigue and feeling unwell, fever
- abnormal cervical smear.

More information (from the diaries kept by women during a clinical trial

with this drug) about the possible side effects 'irregular bleeding (heavy, irregular bleeding)' and 'absence of bleeding' can be found under 'Intermenstrual bleeding' and 'What to do if you do not have bleeding on day 26 or on (one of) the following day(s)'. Description of certain side effects

#### Description of certain side effects

Side effects that are very rare or whose first symptoms appear later and that are related to the group of combined hormonal contraceptives and that can also occur during the use of Qlaira are listed below (see also section 2 'When should you not use this medicine?' and 'When should you be extra careful with this medicine?').

- liver tumors (benign and malignant)
- erythema nodosum (painful, bluish-red nodules in the skin) and erythema multiforme (skin rash with irregular red spots)
- hypersensitivity reactions (including symptoms such as skin rash, urticaria (hives))
- in women with hereditary angioedema (characterized by sudden swelling of for example the eyes, mouth, throat, etc.) estrogens in combined oral contraceptives can cause or worsen symptoms of angioedema.

In case of impaired liver function, it may be necessary to temporarily stop using combined oral contraceptives.

#### Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

#### 5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.

There are no special storage conditions for this medicine.

Do not use this medicine after the expiry date. It can be found on the wallet 'EXP'. It includes a month and a year. The last day of that month is the expiry date. Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your

pharmacist what to do with medicines you no longer use. They will be destroyed responsibly and will not enter the environment. 6. CONTENTS OF THE PACK AND OTHER INFORMATION What substances are in this medicine?

The active substances in this medicine are

What substances are in this medicine?

The active substances in this medicine are estradiol valerate of estradiol valerate combined with dienogest.

Each Qlairawallet (28 film-coated tablets) contains 26 active tablets in 4 different colors in row 1, 2, 3, and 4 and additionally 2 white, inactive tablets in row 4.

Composition of the colored tablets with one or two active substances:

2 dark yellow tablets each with 3 mg estradiol valerate

5 medium red tablets each with 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 1 mg estradiol valerate

Composition of the white, non-active tablets:

These tablets contain no active substance.

The other ingredients in the colored, active tablets are:

Tablet core: lactose monohydrate, corn starch, pre-gelatinized corn starch, povidone K25 (E1201), magnesium stearate (E572)

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

The other ingredients in the white, non-active tablets are:

Tablet core: lactose monohydrate, corn starch, povidone K25 (E1201), magnesium stearate (E572) Tablet coating: hypromellose type 2910 (E464), talc (E553b), titanium dioxide (E171)

What does Qlairair look like and how much is in a package

Qlairairtablets are film-coated tablets: the core of the tablet is coated with a layer.

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 row 2, 3, and 4, 2 dark red tablets in row 4, and additionally 2 white tablets in row 4.

The dark yellow, active tablet is round with convex sides; one side is marked with the letters 'DD' in a regular hexagon.

The medium red, active tablet is round with convex sides; one side is marked with the letters 'DJ' in a regular hexagon.

The light yellow, active tablet is round with convex sides; one side is marked with the letters 'DH' in a regular hexagon.

The dark red, active tablet is round with convex sides; one side is marked with the letters 'DN' in a regular hexagon.

The white, inactive tablet is round with convex sides; one side is marked with the letters 'DT' in a regular hexagon.

Qlaira is available in packages of 1, 3, or 6 wallets each containing 28 tablets.  
Not all pack sizes mentioned are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Bayer B.V.

Siriusdreef 36

2132 WT Hoofddorp

For information:

Bayer B.V., P.O. Box 88, 2130 AB Hoofddorp

Manufacturer

Bayer Weimar GmbH und Co. KG and Bayer AG

Döbereinerstr. 20, 99427 Weimar Müllerstrasse 178, 13353 Berlin

Germany Germany

Registered under RVG 101491.

This medicine is registered in member states of the European Economic Area under the following names:

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

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