SELECT THE REQUIRED INFORMATION

PROFESSIONAL INFORMATION

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before you start taking QLAIRA.

- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor or your pharmacist.**
- **QLAIRA 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.**

SCHEDULING STATUS: S3

NAME OF THE MEDICINAL PRODUCT:

QLAIRA

Film-coated tablets

1. WHAT QLAIRA CONTAINS:

Actives:
Estradiol valerate/dienogest
Each wallet (28 film-coated tablets) contains in the following order:
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 1 mg estradiol valerate;
2 white placebo tablets.

List of inactive ingredients:
Active tablets:
Lactose monohydrate, maize starch, pregelatinised maize starch, povidone 25, magnesium stearate, hypromellose, macrogol 6000, talc, titanium dioxide (E171, CI 77891), ferric oxide yellow (E172, CI 77492) and/or ferric oxide red (E172, CI 77491).
Placebos:
Lactose monohydrate, maize starch, povidone 25, magnesium stearate, hypromellose, talc, titanium dioxide.

2. WHAT QLAIRA IS USED FOR:

QLAIRA is a contraceptive pill and is used to prevent pregnancy.

3. DO NOT USE QLAIRA:

Do not use QLAIRA, if you have any of the conditions listed below. If any of these apply to you, tell your doctor before starting to use QLAIRA. Your doctor may advise you to use a different type of oral contraceptive or an entirely different (non-hormonal) method of birth control.

3.1 Do not use QLAIRA:

if you:

- are pregnant;
- are allergic to estradiol valerate or dienogest, or any of the other ingredients of QLAIRA. This may cause itching, rash or swelling.

or if you have ever had:

- a blood clot in a blood vessel of the leg (thrombosis), of the lung (pulmonary embolism) or other organs;
- a heart attack or stroke**;**

- a disease that can be (i) an indicator of a future heart attack (for example, angina pectoris which causes severe chest pain) or (ii) of a stroke (for example, a minor stroke with no residual effects);
- a certain kind of migraine (with so-called focal neurological symptoms);
- diabetes with damaged blood vessels;
- inflammation of the pancreas (pancreatitis);
- liver disease and your liver function is still not normal;
- a tumour of the liver;
- cancer or suspected cancer of the breast or genitals;
- any unexplained bleeding from the vagina.

Before you use QLAIRA:
Before starting QLAIRA, a complete medical history (including family history) should be taken and pregnancy must be ruled out by your doctor. Blood pressure should be measured and a physical examination should be performed. This examination should be repeated at least once a year during the use of QLAIRA.
QLAIRA does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

3.2 Take special care with QLAIRA:

In some situations you need to take special care while taking QLAIRA and your doctor may need to examine you regularly. Consult your doctor before starting to use QLAIRA if any of the following conditions apply to you or if any of them develop or worsen while you are taking QLAIRA**:**

- increased blood pressure;
- disease of the liver or gall bladder;
- jaundice;
- increased fat content in your blood (increased cholesterol and/or triglycerides increase the risk of thrombosis or pancreatitis);
- diabetes;
- Crohn's disease or inflammatory bowel disease (ulcerative colitis);
- a blood disease called haemolytic uraemic syndrome (HUS) that causes kidney damage;
- sickle cell disease;
- epilepsy (see "Using other medicines with QLAIRA");
- a disease of the immune system called systemic lupus erythematosus (SLE);
- surgery or prolonged period of immobilization;
- 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);
- 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;
- hereditary angioedema. Consult your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing. Products containing oestrogens may induce or worsen symptoms of angioedema.

The risk of venous blood clots in users of QLAIRA increases:

- with increasing age;
- if you are overweight;
- if one of your close relatives has had a blood clot in the leg, lung (pulmonary embolism), or other organ at a young age;
- if you need surgery, if you have had a serious accident, or if you have any prolonged period of immobilisation. It is important to tell your doctor that you are using QLAIRA as the treatment may have to be stopped. Your doctor will tell you when to start QLAIRA again;
- if you suffer from inflammation of your veins (superficial phlebitis) or varicose veins.

The use of QLAIRA has been linked to an increased risk of a blood clot in the artery (arterial thrombosis), for example, in the blood vessels of the heart (heart attack) or the brain (stroke).

The risk of arterial blood clots in users of QLAIRA increases:
- if you smoke. You are strongly advised to stop smoking when you use the pill, especially if you are over 35 years old;
- if you have a high level of blood cholesterol or triglycerides;
- if you are overweight;
- if one of your close relatives had a heart attack or stroke at a young age;
- if you have high blood pressure;
- if you suffer from migraine;
- if you have a problem with your heart (valve disorder, a disturbance of the heart rhythm).

Stop taking QLAIRA and contact your doctor immediately if you notice possible signs of a blood clot or a stroke such as:
- severe pain and/or swelling in one of your legs;
- sudden severe pain in the chest which may spread to the left arm;
- sudden breathlessness;
- sudden cough with no obvious cause;
- any unusual, severe or long-lasting headache, or worsening of migraines;
- partial or complete blindness, or double vision;
- difficulty in speaking, or inability to speak;
- giddiness or fainting;
- sudden changes to your hearing, sense of smell, or taste;
- weakness, strange feeling, or numbness in any part of your body.

Directly after giving birth, women are at an increased risk of blood clots so you should ask your doctor how soon after delivery you can start taking QLAIRA.

QLAIRA and cancer:
- **Breast cancer** has been observed slightly more often in women using combined oral contraceptives (COCs), but it is not known whether this is caused by the medicine. The risk of breast tumours becomes gradually less after stopping the COCs. 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.

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). If unexpected bleeding occurs more than 3 months, 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):
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 unlikely that you are pregnant.
If you have taken the tablets incorrectly or if the expected bleeding does not happen twice in two consecutive months, you may be pregnant. Contact your doctor immediately. Only start the next wallet if you are sure that you are not pregnant.

3.3 Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby while taking QLAIRA, please consult your doctor, pharmacist or other healthcare professional for advice.

Do not take QLAIRA if you are pregnant. 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 want to stop taking QLAIRA”).
In general you should not take QLAIRA while you are breastfeeding. If you want to take the pill while you are breastfeeding you should contact your doctor.

3.4 Using other medicines with QLAIRA:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of QLAIRA with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Some medicines can make QLAIRA less effective in preventing pregnancy, or 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 infections (e.g. ritonavir, nevirapine), other infections (antibiotics such as penicillins, tetracyclines, griseofulvin) and the herbal remedy St. John's wort.

Some medicines can increase the levels of the active substances of QLAIRA in the blood. Inform your doctor if you are using: antifungal medicines containing ketoconazole, antibiotics containing erythromycin.

QLAIRA may influence the effect of other medicines, e.g. the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures).

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

4. HOW TO TAKE QLAIRA:

Do not share medicines prescribed for you with others.
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.
QLAIRA, when taken correctly, has a failure rate of approximately 1 % per year. The failure rate may increase when pills are missed or taken incorrectly.

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 days 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 or ever before:*
  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 days 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 breastfeeding, read the section on "Pregnancy and breastfeeding".

If you take more QLAIRA than you should:

There are no reports of any serious harmful effects of taking too many QLAIRA tablets.
If you take several active tablets at once, you may feel sick or throw up. You 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 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 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.**

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 tablets during **days 3 to 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 to 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.

Missed pill chart

<table>
<tr><td>Contact your doctor straight away if:</td><td colspan="2">➢ You have had sex in the 7 days prior to:
o Forgetting to start a new wallet
o Missing one or more pills on days 3 to 9
➢ You missed two or more coloured pills</td></tr>
<tr><td rowspan="4">If you only missed 1 pill on (more than 12 hours late):</td><td>Day 1 - 17</td><td>➢ Take the missed pill and continue taking the pills as usual (this may mean two pills in one day)
➢ Use additional contraception for the next 9 days</td></tr>
<tr><td>Day 18 - 24</td><td>➢ Do not take the missed pill
➢ Start immediately with the next wallet
➢ Use additional contraception for the next 9 days</td></tr>
<tr><td>Day 25 - 26</td><td>➢ Take the missed pill and continue taking the pills as usual (this may mean two pills in one day)
➢ Use additional contraception for the next 9 days</td></tr>
<tr><td>Day 27 - 28</td><td>➢ Discard the missed pill and continue taking the pills as usual
➢ No additional contraception necessary</td></tr>
</table>

Use in children:

QLAIRA is not intended for girls under the age of 18 years.

What to do if you vomit or have severe diarrhoea:

If you throw up within 3 to 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 another tablet from another wallet 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 want to 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 QLAIRA, ask your doctor or pharmacist.

5. POSSIBLE SIDE EFFECTS:

Not all side effects reported for QLAIRA are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

QLAIRA can cause side effects although not everybody gets them. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet. Please tell your doctor or pharmacist.

The following side effects have been linked with the use of QLAIRA:
Headache, acne, breast pain, breast discomfort, heavy irregular bleeding, weight gain, thrush (vaginal candidiasis), growths in the uterus, depression, mood swings, decreased interest in sex, sleep disorder, migraine, high blood pressure, abdominal pain, nausea, increased alanine aminotransferase (a liver function indicator), hair loss, vaginal discharge, no periods, painful

periods, heavy periods, premenstrual syndrome, ovarian cyst, irritability, feeling generally unwell, swelling of parts of your body, e.g. ankles (oedema), weight loss, herpes simplex, a fungal infection of the eye (presumed ocular histoplasmosis syndrome), tinea versicolor (a fungal infection of the skin), benign breast nodules, liver nodules, increased appetite, aggression, increased interest in sex, nervousness, restlessness, reduced attention, migraine with aura, tension headache, contact lens intolerance, hot flushes, low blood pressure, painful veins, bloating, diarrhoea, vomiting, golden brown pigment patches (chloasma) and other pigmentation disorders, allergic skin reactions, excessive hair growth, itching, skin tightness, hives, muscle spasms, sensation of heaviness, vulvovaginal dryness.

In addition to the above mentioned side effects, the skin disorders erythema nodosum, erythema multiforme, as well as breast discharge and hypersensitivity have occurred in women using combined pills containing ethinylestradiol.

6. STORING AND DISPOSING OF QLAIRA:

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.
Store at or below 25 °C.
Do not use after expiry date stated on the carton.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF QLAIRA:

QLAIRA tablets are film-coated tablets; the core of the tablet is covered with a coating. The tablets are either dark yellow, medium red, light yellow, dark red or white. They are round with biconvex faces, one side embossed with the letters “DD” or “DJ” or “DH” or “DN” or “DT”, respectively in a regular hexagon.
QLAIRA is available in packs of 1, 3, or 6 wallets each containing 28 tablets.
The blister packs consist of clear transparent films made of polyvinyl chloride and metallic foils made of hard tempered aluminum. The blister is glued into a carton wallet.

8. IDENTIFICATION OF QLAIRA:

Each wallet of QLAIRA contains 26 active tablets in 4 different colours in rows 1, 2, 3 and 4 i.e.
2 dark yellow tablets,
5 medium red tablets,
17 light yellow tablets,
2 dark red tablets,
and 2 white placebo tablets in row 4.

9. REGISTRATION NUMBER:

43/18.8/0591

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Bayer (Pty) Ltd
(Reg No: 1968/011192/07)
27 Wrench Road
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1609

11. DATE OF PUBLICATION:

30 September 2011