

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using QLAIRA?

QLAIRA contains the active ingredients estradiol valerate and dienogest. QLAIRA is a combined oral contraceptive, commonly known as a 'birth control pill' or 'the Pill'.

For more information, see Section [1. Why am I using QLAIRA?](#) in the full CMI.

2. What should I know before I use QLAIRA?

Do not use if you have ever had an allergic reaction to QLAIRA or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use QLAIRA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with QLAIRA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use QLAIRA?

- Take one tablet daily at about the same time each day.
- You must take QLAIRA every day regardless of how often you have sex.
- Swallow the tablet whole with a full glass of water. It does not matter if you take it before or after food.

More instructions can be found in Section [4. How do I use QLAIRA?](#) in the full CMI.

5. What should I know while using QLAIRA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using QLAIRA.• If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the test results of some tests.• Have regular check-ups with your doctor. When you are taking QLAIRA, your doctor will tell you to return for regular check-ups, including getting a Cervical Screening Test.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking your medicine or change the dosage without checking with your doctor. You may become pregnant if you are not using any other contraceptive and you stop taking QLAIRA, or do not take a tablet every day.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the blister pack until it is time to take them.• Keep your tablets in a cool dry place where the temperature stays below 30°C.

For more information, see Section [5. What should I know while using QLAIRA?](#) in the full CMI.

6. Are there any side effects?

Common side effects include headache (including migraines), stomach pain, acne, no periods, painful periods, irregular bleeding or spotting, unusual discharge or other symptoms of a vaginal infection, breast tenderness or pain, changes in weight, mood changes (including depression), sleeping problems, decreased libido, nausea, fatigue.

Serious side effects include jaundice (yellowing skin or eyes); signs of a blood clot, e.g. breathlessness, sudden weakness/pins and needles, sudden stomach pains, fainting, unusual headaches or migraines that are worse than usual, sudden problems speaking, sudden trouble walking, pain in chest, arms or below breast bone, discomfort in your back; coughing up blood; unexplained vaginal bleeding; breast lumps. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about using QLAIRA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using QLAIRA.**

Where to find information in this leaflet:

- [1. Why am I using QLAIRA?](#)
- [2. What should I know before I use QLAIRA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use QLAIRA?](#)
- [5. What should I know while using QLAIRA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using QLAIRA?

QLAIRA contains the active ingredient **estradiol valerate and dienogest**.

QLAIRA is a **combined oral contraceptive, commonly known as a 'birth control pill' or 'the Pill'**.

QLAIRA is used to prevent pregnancy. It is also used for the treatment of heavy and/or prolonged menstrual bleeding (not caused by any underlying disease) in women who wish to use oral contraception.

While taking QLAIRA you may also experience the following benefits:

- More regular and lighter periods – potentially resulting in a decrease in anaemia (iron deficiency)
- a decrease in period pain

Some conditions such as pelvic inflammatory disease, ovarian cysts, ectopic pregnancy (where the foetus is carried outside of your womb), lumpy breasts and cancer of the uterus (womb) and ovaries may be less common in women taking QLAIRA.

QLAIRA contains two female sex hormones called estradiol valerate (an estrogen) and dienogest (a progestogen).

The estrogen in QLAIRA (estradiol valerate) is broken down in the body into a hormone called 17 β -estradiol, which is identical to the natural estrogen produced by the female body. The estrogen in QLAIRA is therefore different from the synthetic estrogen (known as ethinylestradiol) usually used in other forms of the Pill.

When taken correctly, QLAIRA prevents you from becoming pregnant by:

- inhibiting ovulation (egg release)
- changing the cervical mucus consistency, making it more difficult for the sperm to reach the egg

- changing the lining of the uterus, making it less suitable for implantation.

When the Pill is taken by women under close observation in clinical trials, it is more than 99% effective in preventing pregnancy. However, in real life the Pill is around 92% effective. This is because pills might be missed, or taken with medicines that may interfere with their effectiveness, or may not be absorbed due to vomiting and diarrhoea.

Like all oral contraceptives, QLAIRA is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted infections.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I use QLARIA?

Warnings

Do not use QLAIRA if:

- you are allergic to estradiol valerate and/or dienogest, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty in breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take QLAIRA if you are concerned about an increased risk of blood clots. Blood clots are rare. Very occasionally blood clots may cause serious permanent disability, and may even be fatal.

All combined oral contraceptive pills, including QLAIRA, increase the risk of having a blood clot. However the risk of having a blood clot when taking QLAIRA is less than the risk of having a blood clot during pregnancy.

Do not take QLAIRA if you are concerned about an increased risk of blood clots because of age or smoking.

The risk of having a heart attack or stroke increases as you get older. It also increases if you smoke. You should stop smoking when taking QLAIRA, especially if you are older than 35 years of age.

Do not take QLAIRA if you have, or have had:

- blood clots in:

- the blood vessels of the legs (deep vein thrombosis - DVT)
- the lungs (pulmonary embolism - PE)
- the heart (heart attack)
- the brain (stroke)
- other parts of the body
- any blood clotting disorders such as Protein C deficiency, Protein S deficiency, Leiden Factor V mutation,
- Antithrombin III deficiency or other inherited blood clotting conditions
- a confirmed blood test showing:
 - increased levels of homocysteine
 - antiphospholipid antibodies (APLAs) e.g. anticardiolipin-antibodies and lupus anticoagulant. These may increase your risk for blood clots or pregnancy losses (miscarriage).
- major surgery after which you have not been able to move around for a period of time
- angina (chest pain)
- a mini-stroke (also known as TIA or transient ischaemic attack)
- migraine, where you have also had problems with seeing, speaking or had weakness or numbness in any part of your body
- high risk of blood clots due to conditions such as diabetes with blood vessel damage, severe high blood pressure or severe high or low level of fats in your blood
- pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood
- severe liver disease and your liver function has not returned to normal
- cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs)
- a benign or malignant liver tumour
- unexplained vaginal bleeding.

If any of these conditions appear for the first time while using QLAIRA, stop taking it at once and tell your doctor. In the meantime use non-hormonal (barrier) methods of contraception (such as condoms or a diaphragm).

Do not take this medicine if you are pregnant or think you might be pregnant.

Do not give this medicine to a child. QLAIRA is not intended for use in females whose periods have not yet started.

Check with your doctor if:

- you have, or have had any of the following medical conditions:
 - diabetes
 - high blood pressure
 - heart valve disorders or certain heart rhythm disorders
 - migraine
 - cancer
- you take any medicines for any other condition

- you smoke
- you or anyone in your immediate family has had blood clots in the legs (DVT) or lungs (PE), a heart attack, a stroke, breast cancer or high cholesterol.

Ask your doctor to check if you:

- are overweight
- have any hereditary or acquired conditions that may make it more likely for you to get blood clots
- have high cholesterol or triglycerides
- have liver disease
- have jaundice (yellowing of the skin) and/or pruritus (itching of the skin) related to cholestasis (condition in which the flow of bile from the liver stops or slows)
- have gall bladder disease
- have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- have systemic lupus erythematosus (SLE - a disease affecting the skin, joints and kidneys)
- have haemolytic uraemic syndrome (HUS - a disorder of blood coagulation causing failure of the kidneys)
- have sickle cell disease
- have a condition that occurred for the first time, or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, a metabolic disease called porphyria, a skin disease called herpes gestationis, a neurological disease called Sydenham's chorea)
- have chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face) – if so, avoid exposure to the sun or ultraviolet radiation
- have hereditary angioedema – you should see your doctor immediately if you experience symptoms of angioedema, such as swollen face, tongue and/or pharynx and/or difficulty swallowing, or hives together with difficulty in breathing
- you have an intolerance to some sugars. QLAIRA contains lactose.

If any of the above conditions appear for the first time, recur or worsen while using QLAIRA, you should tell your doctor.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. QLAIRA is generally not recommended if you are breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines/foods and QLaira may interfere with each other. These include:

- medicines used to treat tuberculosis such as rifampicin, rifabutin
- medicines used to treat epilepsy such as phenytoin, primidone, barbiturates (e.g. phenobarbitone), carbamazepine, oxcarbazepine, topiramate, felbamate, lamotrigine
- medicines used to treat HIV, such as ritonavir or nevirapine
- some medicines used to treat Hepatitis C Virus (HCV) such as boceprevir, telaprevir
- macrolide antibiotics such as clarithromycin and erythromycin
- medicines used to treat fungal infections, such as ketoconazole, itraconazole, voriconazole, fluconazole and griseofulvin
- herbal medicines containing St John's Wort
- blood pressure medication such as verapamil, diltiazem
- medicines used to treat depression such as nefazodone, fluvoxamine
- antacids such as cimetidine
- grapefruit juice.

These medicines/foods may be affected by QLaira or may affect how well it works. Your doctor may need to alter the dose of your medicine, or prescribe a different medicine.

You may need to use an additional barrier method of contraception (such as condoms or a diaphragm) while you are taking any of these medicines with QLaira and for some time after stopping them.

Your doctor will be able to tell you how long you will need to use additional contraceptive methods.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect QLaira.

4. How do I use QLaira?

How much to take

Take one tablet daily at about the same time each day. You must take QLaira every day regardless of how often you have sex. This will also help you remember when to take it.

Swallow the tablet whole with a full glass of water. It does not matter if you take it before or after food.

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

Usually your period will start when you are taking the second dark red tablet or the white tablets and may not have finished before you start the next packet. Some women still experience bleeding after taking the first tablets of the new packet.

Tablets should be taken continuously so the next packet should be started even if bleeding has not stopped. This means that you should start your following packet on the same day of the week as the current packet and that your period should occur on the same days each month.

Preparation of the packet

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". Remember to use the same weekday sticker strip (for example, "WED") for your next packet.

Stick the weekday sticker strip along the top of the QLaira packet 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 tablet on a particular day. Follow the direction of the arrow on the packet until all 28 tablets have been taken.

Discard the unused weekday sticker strips.

When to take QLaira

If you are starting QLaira after a natural cycle, and you have not used a hormonal contraceptive during the previous month, start on the first day of your period, i.e. on the first day of your menstrual bleeding. If you take QLaira in this way, you are protected against pregnancy immediately.

Your doctor will advise you when to start if you:

- are taking QLaira after having a baby
- have had a miscarriage or an abortion

Changing from another contraceptive

Changing from a combined oral contraceptive:

Start taking QLaira on the day after taking the last active tablet in your previous Pill pack.

If you are not sure which were the active/inactive tablets in your previous Pill pack, ask your doctor or pharmacist. Your previous Pill pack may have different colour tablets to those of QLaira.

Changing from a progestogen-only pill ('minipill'):

Stop taking the minipill on any day and start taking QLAIIRA at the same time the day after you took your last minipill.

You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 9 days of tablet-taking when having intercourse.

Changing from a progestogen-only injection, implant or intrauterine system (IUS):

Start taking QLAIIRA when your next injection is due, or on the day that your implant or IUS is removed.

You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 9 days of tablet-taking when having intercourse.

Changing from a vaginal ring:

Start QLAIIRA on the day of removal of the vaginal ring or follow the advice of your doctor.

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

Stopping QLAIIRA

You can stop taking QLAIIRA at any time. If you are considering becoming pregnant, it is recommended that you begin taking a vitamin supplement containing folic acid. It is best that you start taking folic acid before you stop taking QLAIIRA and not stop until your doctor advises this. Ask your doctor or pharmacist about suitable supplements. It is both safe and recommended that you take folic acid during pregnancy.

If you forget to take QLAIIRA

Inactive tablets:

If you miss a white tablet (2 tablets at the end of the packet), you do not need to take them later because they do not contain any active ingredients. However, it is important that you discard the missed white tablet(s) to make sure that the number of days between taking active 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 or diaphragm.

Take the tablets according to the following principles. See also the 'Summary of advice if you missed a tablet' chart at the end of this leaflet.

- If you are less than 12 hours late taking a tablet, protection against pregnancy is not reduced. Take the tablet as soon as you remember and then continue taking further tablets again at the usual time.
- If you are more than 12 hours late taking a tablet, 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 or diaphragm. You may also need to start a new packet immediately. **You must refer to the 'Summary of advice if you missed a tablet' chart at the end of this leaflet for details.**

- If more than one tablet is forgotten in a packet, contact your doctor

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

If you have forgotten to start a new packet, or if you have missed one or more tablets during Days 3-9 of your packet, 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 of becoming pregnant.

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

Please see the chart at the end of this leaflet for the 'Summary of advice if you missed a tablet'.

Ask your doctor or pharmacist to answer any questions you may have.

If you take too much QLAIIRA

If you think that you have used too much [medicine name], you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26** in Australia or **0800 764 766** in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using QLAIIRA?

Things you should do

Tell any doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Have regular check-ups with your doctor.

When you are taking QLAIIRA, your doctor will tell you to return for regular check-ups, including getting a Cervical Screening Test. Your doctor will advise how often you need a Cervical Screening Test. A Cervical Screening Test can detect abnormal cells lining the cervix. Sometimes abnormal cells can progress to cancer.

If you are about to start on any new medicine, remind your doctor and pharmacist that you are taking QLAIRA.

Stop taking QLAIRA and call your doctor straight away if you notice the following signs:

- one-sided swelling of the leg and/or foot or along a vein in the leg
- pain or tenderness in the leg which may be felt only when standing or walking
- increased warmth in the affected leg; red or discoloured skin on the leg
- sudden onset of unexplained shortness of breath or rapid breathing
- sudden coughing or coughing up of blood
- sharp chest pain or sudden severe pain in the chest which may increase with deep breathing
- severe light headedness or dizziness
- rapid or irregular heartbeat
- sudden pain, swelling and slight blue discoloration of an extremity
- sudden numbness or weakness of the face, arm or leg, especially on one side of the body
- sudden trouble walking, dizziness, loss of balance or coordination
- sudden confusion, slurred speech or aphasia; sudden partial or complete loss of vision, double vision, painless blurring of vision which can progress to loss of vision
- sudden, severe or prolonged headache with no known cause
- loss of consciousness or fainting with or without seizure
- pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the chest arm, or below the breastbone
- discomfort radiating to the back, jaw, throat, arm, stomach
- feeling of being full, having indigestion or choking
- sweating, nausea, vomiting
- extreme weakness and anxiety

If you are going to have surgery, tell the surgeon or anaesthetist beforehand that you are taking QLAIRA.

The risk of having blood clots is temporarily increased as a result of major surgery, any surgery to the legs or pelvis, neurosurgery or major trauma. In women who take QLAIRA, the risk may be higher.

In women at risk of prolonged immobilisation (including major surgery, any surgery to the legs or pelvis, neurosurgery, or major trauma), your doctor may tell you to stop taking (in the case of elective surgery at least four weeks in advance) and not resume until two weeks after complete remobilisation. Another method of contraception should be used to avoid unintentional pregnancy. Your doctor may prescribe other treatment (e.g. treatment for blood clots) if QLAIRA has not been discontinued in advance.

Other risk factors for blood clotting include temporary immobilisation including air travel of greater than 4 hours, particularly in women with other risk factors. **Consult your doctor if you plan to air travel for greater than 4 hours.**

Consult your doctor if you develop high blood pressure while taking QLAIRA – you may be told to stop taking it.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you vomit within 3-4 hours or you have severe diarrhoea after taking any of the active tablets, the active ingredients may not have been completely absorbed. This is like missing a tablet. Follow the advice for missed tablets.

If you have unexpected bleeding and it continues, becomes heavy, or occurs again, tell your doctor.

When taking these tablets for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary products, but continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to QLAIRA, usually after about 3 months.

If you have missed a period, but you have taken all your tablets, it is unlikely that you are pregnant as long as:

- you have taken the active tablets at the right time
- you have not been taking medicine(s) that may interfere with QLAIRA
- you have not vomited or had severe diarrhoea during this cycle

If this is so, continue to take QLAIRA as usual. If you have any concerns consult your doctor or pharmacist.

If you miss your period twice in a row, you may be pregnant even if you have taken QLAIRA correctly. Stop taking QLAIRA and seek advice from your doctor. You must use a non-hormonal method of contraception (such as condoms or a diaphragm) until your doctor rules out pregnancy.

QLAIRA will not protect you from HIV-AIDS or any other Sexually Transmitted Infections (STIs), such as chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, human papilloma virus and syphilis.

To protect yourself from STIs, you will need to use condoms.

Things you should not do

- Do not stop using this medicine or change the dosage without checking with your doctor. You may become pregnant if you are not using any other contraceptive and you stop taking QLAIRA, or do not take a tablet every day as directed.
- Do not take QLAIRA to treat any other conditions, unless your doctor tells you to.
- Do not give your medicine to anyone else.

Driving or using machines

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration. However, adverse effects of QLAIRA include dizziness and fatigue that could affect the ability to drive or use machines

Looking after your medicine

- Keep your tablets in a cool dry place where the temperature stays below 30°C.
- Keep your tablets in the packet until it is time to take them. If you take the tablets out of the packet they may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Skin-related:</p> <ul style="list-style-type: none"> • acne <p>General:</p> <ul style="list-style-type: none"> • fatigue <p>Gastrointestinal-related:</p> <ul style="list-style-type: none"> • nausea • stomach pain <p>Metabolic:</p> <ul style="list-style-type: none"> • changes in weight <p>Neurological:</p> <ul style="list-style-type: none"> • headache, including migraines • mood changes, including depression or decreased sex drive • sleeping problems <p>Reproductive system-related:</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> • breast tenderness or pain • no periods, painful periods, irregular bleeding or spotting • symptoms of vaginal yeast infection, such as unusual vaginal discharge, itching and burning of the vagina and labia (skin around vaginal opening) 	
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Serious side effects

Serious side effects	What to do
<p>Blood clot-related:</p> <ul style="list-style-type: none"> • pain in the chest, arm or below the breastbone • pain or discomfort that goes to your back • breathlessness and/or difficulty breathing • swelling, pain or tenderness of one leg • sudden weakness, numbness or bad 'pins and needles' of the face, arm or leg, especially on one side of the body • sudden trouble walking, dizziness, loss of balance or coordination • severe, sudden stomach pains • a fainting attack or you collapse • unusual headaches or migraines that are worse than usual • sudden problems with speaking, seeing or understanding what people are saying to you <p>Liver-related:</p> <ul style="list-style-type: none"> • jaundice (yellowing skin or yellowing eyes) <p>Bleeding-related:</p> <ul style="list-style-type: none"> • you cough up blood <p>Reproductive system-related:</p> <ul style="list-style-type: none"> • breast lumps • unexplained vaginal bleeding 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Blood clots and the Pill

Blood clots may block blood vessels in your body. This type of blood clot is also called thrombosis.

Blood clots sometimes occur in the deep veins of the legs. If a blood clot breaks away from the veins where it has formed, it may reach and block the blood vessels of the lungs, causing pulmonary embolism.

Blood clots can also occur in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke).

Blood clots are a rare occurrence and can develop whether or not you are taking the Pill. They can also happen during pregnancy. The risk of having blood clots is higher in the Pill users than in non users, but not as high as during pregnancy.

The risk of a blood clot is highest during the first year of taking the Pill for the first time, or when re-starting after having a break from the Pill for 4 weeks or more.

Nonetheless, if you notice possible signs of a blood clot, stop taking QLAIRA and consult your doctor immediately. To prevent pregnancy, you must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm).

If you are concerned about an increased risk of blood clots while taking QLAIRA, speak to your doctor.

Cancer and the Pill

Breast cancer has been diagnosed slightly more often in women who take the Pill than in women of the same age who do not take the Pill.

This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after women stop taking the Pill.

It is not known whether the difference is caused by the Pill. It may be that these women were examined more often, so that the breast cancer was noticed earlier.

It is important that you check your breasts regularly and contact your doctor if you feel any lumps.

In rare cases benign liver tumours and, even more rarely, malignant liver tumours have been reported in users of the Pill. These tumours may lead to internal bleeding.

Contact your doctor immediately if you have severe pain in your abdomen.

Cervical cancer has been reported to occur more often in women who have been taking the Pill for a long time. This finding may not be caused by the Pill, but may be related to sexual behaviour and other factors.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems or in New Zealand at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What QLAIRA contains

Each coloured active tablet contains:	
Active ingredients (main ingredients)	The different coloured tablets contain one or two active ingredients: <ul style="list-style-type: none"> • 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.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • lactose monohydrate • maize starch • pregelatinised maize starch • povidone • magnesium stearate • hypromellose • macrogol 6000 • purified talc • titanium dioxide • iron oxide yellow and/or iron oxide red.
Potential allergens	Lactose monohydrate
Each white inactive tablet contains:	
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • lactose monohydrate • maize starch • povidone • magnesium stearate • hypromellose • purified talc • titanium dioxide
Potential allergens	Lactose monohydrate

Do not take this medicine if you are allergic to any of these ingredients.

Tablets do not contain sucrose, gluten, tartrazine or azo dyes.

What QLAIRA looks like

QLAIRA tablets are film-coated tablets. The tablets are either dark yellow, medium red, light yellow, dark red or white. They are round with one side embossed with the letters 'DD' or 'DJ' or 'DH' or 'DN' or 'DT', respectively in a regular hexagon.

QLAIRA comes in a pack containing either 1 or 3 packets (also called a 'wallet'). Each packet of QLAIRA contains 26

coloured active (hormone) tablets in rows 1, 2, 3 and 4 and 2 white inactive tablets in row 4 (AUST R 149319).

Who distributes QLAIRA

Bayer Australia Ltd
ABN 22 000 138 714
875 Pacific Highway
Pymble, NSW 2073

Bayer New Zealand Limited
B:HIVE Building, 74 Taharoto Rd
Smales Farm, Takapuna
Auckland, 0622
New Zealand

See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

See MEDSAFE website (www.medsafe.govt.nz) for latest New Zealand Consumer Medicine Information.

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SUMMARY OF ADVICE IF YOU MISSED A TABLET

