

QLAIRA®

Contraceptive tablets for women

oestradiol valerate and dienogest

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Qlaira. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Qlaira against the benefits they expect it will have for you.

If you have any concerns, or are unsure about taking this medicine, ask your doctor or pharmacist for more advice.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT QLAIRA IS USED FOR

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, fibrocystic breast changes and cancer of the uterus (womb) and ovaries may be less common in women taking the Pill.

Qlaira contains two female sex hormones called oestradiol valerate (an oestrogen) and dienogest (a progestogen). The oestrogen in Qlaira (oestradiol valerate) is broken down in the body into a hormone called 17β-oestradiol, which is identical to the natural oestrogen produced by the female body. The oestrogen in Qlaira is therefore different from the synthetic oestrogen (known as ethinyloestradiol) 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.

BEFORE YOU TAKE QLAIRA

When you must not take it

Do not take Qlaira if you have an allergy to:

- any medicine containing oestradiol valerate and/or dienogest
- any of the ingredients in Qlaira listed at the end of this leaflet.

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 have, or have had a blood clot 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.

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.

You are more at risk of having a blood clot when you take the Pill. However the risk of having a blood clot when taking the Pill 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 the Pill, especially if you are older than 35 years of age.

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

- angina (chest pain)
- a mini-stroke (also known as TIA or transient ischaemic attack)
- migraine, accompanied by visual symptoms, speech disability, or weakness or numbness in any part of your body
- diabetes mellitus with blood vessel damage

- 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 the Pill, 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.

Do not take this medicine after the expiry date printed on the wallet.

The expiry date is printed on the wallet after "EXP" (e.g. 11 18 refers to November 2018). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

Do not take this medicine if the packaging is torn or shows signs of tampering.

If the packaging is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if:

- 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.

Tell 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
- inflammation of your veins (superficial phlebitis)
- varicose veins
- migraine
- epilepsy

Ask your doctor to check if you:

- are overweight
- have high cholesterol or triglycerides
- have liver disease
- 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

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

Tell your doctor if you are breastfeeding.

Qlaira is generally not recommended if you are breastfeeding.

Qlaira contains lactose.

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

If you have not told your doctor about any of the above, tell him/her before you start taking Qlaira.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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 advise you about how long you will need to use additional contraceptive methods.

Your doctor and pharmacist have more information on medicines that you need to be careful with or avoid while taking this medicine.

HOW TO TAKE QLAIRA

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions printed on the wallet or in this leaflet, ask your doctor or pharmacist for help.

How to take it

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 water. It does not matter if you take it before or after food.

Each wallet 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 wallet. Some women still experience bleeding after taking the first tablets of the new wallet.

Tablets should be taken continuously so the next wallet should be started even if 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 your period should occur on the same days each month.

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”. Remember to use the same weekday sticker strip (for example, “WED”) for your next wallet.

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 tablet on a particular day. Follow the direction of the arrow on the wallet until all 28 tablets have been taken.

Discard the unused weekday sticker strips.

Taking Qlaira for the first time

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 Qlaira at the same time the next day.

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 Qlaira 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 Qlaira 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 Qlaira

You can stop taking Qlaira 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 Qlaira and not stop until your doctor advises this. Seek advice from 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 Qlaira

Inactive tablets:

If you miss a white tablet (2 tablets at the end of the wallet), 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 wallet 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 wallet, contact your doctor.

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

If you have forgotten to start a new wallet, or if you have missed one or more tablets during Days 3-9 of your wallet, there is a risk that you are already pregnant (if you had sex in the 7 days before forgetting the tablet). In that case, contact your doctor. The more tablets you have forgotten (especially those on days 3-24) and the closer they are to the inactive tablet phase, the greater the risk of becoming pregnant.

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 go on to the next wallet.

Please refer to 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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia: 13 11 26 or New Zealand: 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Qlaira.

Do this even if there are no signs of discomfort or poisoning.
You may need medical attention.

WHILE YOU ARE TAKING QLAIRA

Things you must 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 the Pill, your doctor will tell you to return for regular check-ups, including getting a Pap (cervical) smear test. Your doctor will advise how often you need a Pap (cervical) smear test. A Pap (cervical) smear 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 see your doctor immediately if you notice possible signs of thrombosis (blood clot). These include:

- an unusual cough
- severe pain or heaviness in the chest
- breathlessness
- any unusual, severe, or prolonged headache or migraine attack
- partial or complete loss of vision, or double vision
- slurring or speech disability
- sudden changes to your hearing, sense of smell, or taste
- dizziness or fainting
- weakness or numbness in any part of your body
- severe pain in your abdomen

- severe pain, swelling or discolouration in either of your legs.

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

The risk of having a DVT is temporarily increased as a result of an operation or immobilisation (for example, when you have your leg(s) in plaster/ splints). In women who take the Pill, the risk may be higher.

Your doctor may tell you to stop taking the Pill several weeks before surgery, or at the time of immobilisation, and when you can start taking the Pill again. If you notice possible signs of a blood clot, stop taking the Pill and consult your doctor immediately.

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 protection, but continue to take your tablets as normal. Irregular vaginal bleeding usually stops

once your body has adjusted to the Pill, 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 the Pill 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.

What you must not do

Do not take Qlaira to treat any other conditions, unless your doctor tells you to.

Do not give your medicine to anyone else.

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 as directed.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Qlaira.

This medicine helps most women, but it may have unwanted side effects in a few women.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

The following list includes the more common side effects of your Pill. These are usually mild and lessen with time.

If you notice any of the following side effects and they worry you, tell your doctor or pharmacist:

- headache, including migraines
- stomach pain
- acne
- no periods, painful periods, irregular bleeding, spotting or discharge
- breast tenderness or pain
- changes in weight
- mood changes, including depression
- sleeping problems
- decreased libido
- nausea

- fatigue

The following list includes very serious but rare side effects. You may need urgent medical attention or hospitalisation.

If you experience any of the following, tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- pain in the chest, arm, or below the breastbone
- discomfort radiating to the back
- breathlessness and/or difficulty breathing
- swelling, pain or tenderness of one leg or along a vein in the leg
- sudden weakness, numbness or bad ‘pins and needles’ of the face, arm or leg, especially on one side of the body
- sudden problems with speech, understanding or eyesight
- 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

The side effects listed above are possible signs of a blood clot.

- jaundice (yellowing skin or yellowing eyes)
- you cough up blood
- breast lumps
- unexplained vaginal bleeding.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed may also occur in some people.

Thrombosis and the Pill

Thrombosis is the formation of a blood clot that may block a blood vessel.

Thrombosis sometimes occurs in the deep veins of the legs (DVT). If a blood clot breaks away from the veins where it has formed, it may reach and block the arteries of the lungs, causing pulmonary embolism (PE).

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.

Studies involving some types of oral contraceptives have shown that the risk of having blood clots is higher in these 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.

These studies have not been performed with Qlaira. The risk of having a blood clot while taking Qlaira is currently unknown.

Nonetheless, if you notice possible signs of a blood clot, stop taking Qlaira and consult your doctor immediately.

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 lump.

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.

AFTER TAKING QLAIRA

Storage

Keep your tablets in the wallet until it is time to take them. If you take the tablets out of the wallet they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store your tablets or any other medicine in the bathroom or near a sink. Do not leave

medication on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep Qlaira where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed.

Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

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 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 wallets. Each wallet of Qlaira contains 26 coloured active (hormone) tablets in rows 1, 2, 3 and 4 and 2 white inactive tablets in row 4.

Ingredients

Composition of the differently coloured tablets containing one or two active ingredients:

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

- 2 dark red tablets each containing 1 mg oestradiol valerate.

Other ingredients in the coloured active tablets are:

- lactose
- maize starch
- pregelatinised maize starch
- povidone
- magnesium stearate
- hypromellose
- macrogol 6000
- talc
- titanium dioxide
- iron oxide yellow and/or iron oxide red.

The white inactive tablets do not contain active ingredient. The ingredients are:

- lactose
- maize starch
- povidone
- magnesium stearate

- hypromellose
- talc
- titanium dioxide.

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

Supplier

Made in Germany for:

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

Bayer New Zealand Limited
3 Argus Place
Hillcrest North Shore
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New Zealand

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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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Missed a tablet?

See the last page of this leaflet.



Summary of advice if you missed a tablet

