

QLAIRA[®]

Contraceptive tablets for women.

oestradiol valerate and dienogest tablets

Consumer Medicine Information

Introduction

This leaflet answers some common questions about Qlaira. The information and instructions it contains may be different to information for other oral contraceptives you may have taken in the past. 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 is Qlaira?

Qlaira is a combined oral contraceptive, containing 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 17 β -oestradiol, which is identical to the natural oestrogen produced by the female body. The oestrogen in Qlaira is therefore different from the synthetic oestrogen usually used in combined oral contraceptives.

Contraceptive tablets that contain two hormones are called combined oral contraceptives, 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 disease of the womb) in women who wish to use oral contraception.

How Qlaira works

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

- Inhibiting the egg release by stopping it maturing
- 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.

Whilst taking Qlaira you may likely experience lighter and shorter menstrual bleeds.

What Qlaira 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 contains 26 coloured active tablets and 2 white inactive tablets.

What Qlaira contains

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.

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

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

Composition of the white inactive tablets:

These tablets do not contain active ingredient. The ingredients are:

- lactose
- maize starch
- pregelatinised maize starch
- povidone
- magnesium stearate
- hypromellose
- talc
- titanium dioxide.

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

Tablets are gluten free.

Before you take Qlaira

General notes:

Before you can begin taking Qlaira, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure and, depending on your personal situation, may also carry out some other tests.

In this leaflet, several situations are described where you should stop taking Qlaira, or where the reliability of Qlaira may be decreased. In such situations you should either not have sex or you should take extra non-hormonal contraceptive precautions, e.g. use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because Qlaira alters the monthly changes of body temperature and cervical mucus.

Consult your doctor

Tell your doctor if you are planning to become pregnant or are breast-feeding.

Tell your doctor if

- you have allergies to any other medicines, foods, preservatives or dyes
- you smoke
- you are overweight
- you or anyone in your immediate family has had blood clots in the legs (thrombosis), a heart attack, a stroke, breast cancer or high cholesterol.

Tell your doctor if you have, or have had

- diabetes
- high blood pressure
- heart valve disorders or certain heart rhythm disorders
- inflammation of your veins (superficial phlebitis)
- varicose veins
- migraine
- epilepsy
- recent surgery or a prolonged period of immobilisation
- HPV (human papillomavirus) infection

When to take special care with Qlaira

In some situations you need to take special care while taking Qlaira or any other combined oral contraceptive, and your doctor may need to examine you regularly.

Consult your doctor before starting to take Qlaira if any of the following conditions apply to you or if any of them develop or worsen while you are taking Qlaira:

- high cholesterol or triglycerides
- liver disease
- gall bladder disease
- Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- systemic lupus erythematosus (SLE - a disease affecting the skin, joints and kidneys)
- haemolytic uraemic syndrome (HUS - a disorder of blood coagulation causing failure of the kidneys)
- sickle cell disease
- 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)
- chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face) – if so, avoid too much exposure to the sun or ultraviolet radiation
- 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

- depression
- cardiac or renal insufficiency
- deep vein thrombosis, symptoms may include: swelling of one leg or along a vein in a leg; pain or tenderness in a leg; increased warmth in a leg; red or discoloured skin on a leg
- pulmonary embolism, symptoms may include: sudden shortness of breath or rapid breathing; sudden coughing which may bring up blood; sharp chest pain which may increase with deep breathing; sense of anxiety; severe light-headedness or dizziness; rapid or irregular heartbeat
- stroke, symptoms may include: sudden numbness or weakness of the face, arm or leg; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking, dizziness, loss of balance or coordination; sudden headache with no known cause; loss of

consciousness or fainting with or without seizure

- blood clots blocking other arterial blood vessels
- heart attack, symptoms may include: 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; fullness, indigestion or choking feeling; sweating, nausea, vomiting or dizziness; extreme weakness, anxiety, or shortness of breath; rapid or irregular heartbeats.

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

This is not a full list of possible symptoms, so if you have any unusual symptoms, contact your doctor.

What to do if you vomit or have diarrhoea

If you vomit within 3-4 hours of taking an active tablet or you have severe diarrhoea, there is a risk that the active substances in the tablet are not fully absorbed by your body. The situation is almost the same as forgetting a tablet. After vomiting or having diarrhoea, take the next tablet as soon as

possible. You should follow the advice given under “**If you forget to take Qlaira**”. If the vomiting or diarrhoea continues, contact your doctor for advice.

When you must not take Qlaira

Do not take Qlaira if you have an allergy to:

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

Some of the symptoms of an allergic reaction may include:

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

Do not take Qlaira if you have or have had a blood clot in:

- the blood vessels of the legs (deep vein thrombosis)
- the lungs (pulmonary embolism)
- the heart (heart attack)
- the brain (stroke)
- other organs or 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 disabilities, or may even be fatal.

You are more at risk of having a blood clot when you take combined oral contraceptives. But the risk of a venous blood clot when taking combined oral contraceptives is less than the risk 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; have increased cholesterol, triglycerides; are overweight or have high blood pressure. You should stop smoking when using combined oral contraceptives, especially if you are older than 35 years of age.

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

- angina pectoris or chest pain
- severe kidney disease or kidney failure
- 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

- yellowing of the skin (jaundice)
- severe liver disease
- cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs)
- benign or malignant liver tumour
- unexplained vaginal bleeding.

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

Do not take Qlaira if you are breastfeeding.

In general Qlaira is not recommended while breastfeeding. If you want to take combined oral contraceptives while breastfeeding you should talk to your doctor.

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 09 refers to November 2009). The expiry date refers to the last day of that month. If this medicine 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.

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 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
- antibiotics (penicillin, ampicillin, erythromycin, tetracycline)

- medicines used to treat fungal infections, such as ketoconazole and griseofulvin
- cyclosporin, an immunosuppressant medicine
- herbal medicines containing St John's Wort
- medicines used to treat high blood pressure (verapamil, diltiazem)
- medicines used for the treatment of depression (antidepressants)
- cimetidine, a medicine used to treat reflux and ulcers
- grapefruit juice.

These medicines may be affected by Qlaira, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

You may need to use additional barrier methods of contraception (such as condoms or a diaphragm) while you are taking any of these medicines 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

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

Take one tablet of Qlaira every day with a small amount of water.

You may take the tablets with or without food.

You must take Qlaira every day at around the same time every day.

You must take Qlaira every day even if you do not have sex very often.

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 sticker strips.

When to start taking Qlaira

- *If you have not used a contraceptive with hormones during the previous month:* Start taking Qlaira 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.
- *Changing from another combined*

hormonal contraceptive tablet, or combined contraceptive vaginal ring or patch:

Start Qlaira on the day after taking the last active tablet (the last tablet containing the active substances) of your previous combined oral contraceptive. When changing from a combined contraceptive vaginal ring or patch, start taking Qlaira on the day of removal or, follow the advice of your doctor. If you take Qlaira in this way, you are protected against pregnancy immediately.

- *Changing from a progestogen-only method (progestogen-only tablet, injection, implant or a progestogen-releasing ‘IUS’, intrauterine system):* You may switch from the progestogen-only tablet 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 taking Qlaira.
- *After a miscarriage:* Follow the advice of your doctor.
- *After having a baby:*

You can start Qlaira between 21 and 28 days after having a baby. If you start later than day 28, use a barrier method (for example, a condom) during the first 9 days of taking Qlaira. 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.

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

Ask your doctor or pharmacist if you are not sure which active tablets were in your previous oral contraceptive pack.

Your previous oral contraceptive pack may have different colour tablets to those of Qlaira.

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 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 ‘**Summary of advice if you missed a tablet**’ chart for details.

- If you are less than 12 hours late 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 ‘**Summary of advice if you missed a tablet**’ chart for details.
- More than one tablet forgotten in this wallet, contact your doctor.

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

If you have forgotten to start a new wallet, or if

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

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

*Please refer to the chart on the last page of this leaflet for a ‘**Summary of advice if you missed a tablet**’.*

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

What you must do

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

Have regular check ups with your doctor

When you are using a combined oral contraceptive, your doctor will tell you to return for regular check ups, including getting a pap smear test. Your doctor will advise how often you need a pap smear test. A pap 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.

If you need a blood test or other laboratory tests, tell your doctor or the laboratory staff that you are taking a combined oral contraceptive.

Oral contraceptives can affect the results of some tests.

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

The risk of having deep venous thrombosis is temporarily increased as a result of an operation or immobilisation (for example, when you have your leg or legs in plaster or splints). In women who use a combined oral contraceptive, the risk may be yet higher.

The excess risk of thrombosis is highest during the first year a woman uses a combined oral contraceptive. Your doctor may tell you to stop taking the combined oral contraceptive several weeks before surgery, or at the time of immobilisation, and when you can start taking the combined oral contraceptive again. If you notice possible signs of a thrombosis, stop taking the combined oral contraceptive 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.

While on Qlaira ask your doctor to check your blood pressure when you have your woman's health check up.

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

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 combined oral contraceptive, usually after about 3 months.

If you have missed a period, but you have taken all your tablets, it is very unlikely that you are pregnant.

If you have not vomited, had severe diarrhoea, been on any other medication, and have taken the coloured active tablets at the right time (without using any other medicines), then continue to take Qlaira as usual.

If you miss your period twice in a row, you may be pregnant and you should seek advice from your doctor. Do not start the next pack of Qlaira until your doctor has checked that you are not pregnant.

To protect yourself from sexually transmitted diseases (STDs), you will need to use additional barrier contraceptives (e.g. condoms).

Qlaira will not protect you from HIV-AIDs or any other STDs, such as

chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, human papilloma virus and syphilis.

What to do if you vomit or have diarrhoea

If you vomit within 3-4 hours of taking an active tablet or you have severe diarrhoea, there is a risk that the active substances in the combined oral contraceptive are not fully absorbed by your body. The situation is almost the same as forgetting a tablet. After vomiting or having diarrhoea, take the next tablet as soon as possible. You should follow the advice given under “**If you forget to take Qlaira**”. If the vomiting or diarrhoea continues, contact your doctor for advice.

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 this product, ask your doctor or pharmacist.

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.

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 people, but it may have unwanted side effects in a few people. 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.

Tell your doctor or pharmacist if you feel unwell.

Other side effects not listed on the following pages may also occur in some people.

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

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

- headache, migraine
- abdominal pain
- acne
- no periods, painful periods, irregular bleeding (heavy irregular bleeding), heavy periods, uterine/vaginal bleeding including spotting
- breast pain, discomfort or tenderness, nipple pain
- weight changes
- genital discharge
- emotional disorder, mood changes
- sleeping problems
- decreased libido
- nausea
- fatigue

The above list includes common side effects of your medicine. These are usually mild and lessen with time.

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

- any chest pain, rapid or irregular heartbeat
- pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the chest, arm, or below the breastbone
- pain radiating to the back, jaw, throat, arm, stomach
- breathlessness and/or difficulty breathing
- painful swelling in your leg(s) 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
- weakness, numbness or bad ‘pins and needles’ of the face, arm or leg, especially on one side of the body
- severe light headedness or dizziness
- confusion, trouble speaking or understanding
- trouble walking, loss of balance or coordination
- severe abdominal pains
- fullness, indigestion or choking feeling
- fainting or collapse
- sudden, severe or prolonged headaches or migraines that are worse than usual
- trouble seeing in one or both eyes
- yellowing of the skin and/or eyes (jaundice)

- coughing up blood
- breast lumps
- unexplained uterine/vaginal bleeding.

The above list includes possible serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Cancer and combined oral contraceptives

Breast cancer has been diagnosed slightly more often in women who use a combined oral contraceptive than in women of the same age who do not use a combined oral contraceptive. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after women stop using combined oral contraceptives.

It is not known whether the difference is caused by combined oral contraceptives. It may be that these women were examined more often, so that the breast cancer was noticed earlier. 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, even more rarely, malignant liver tumours have been reported in users of combined oral contraceptives. 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 using combined oral contraceptives for a long time. This finding may not be caused by combined oral contraceptives, but may be related to sexual behaviour and other factors.

How to store Qlaira

Keep your tablets in the wallet until it is time to take them.

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

Do not store Qlaira in the bathroom or near a sink. Do not leave this

medicine 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.

Further information

If you require further information contact your doctor or pharmacist.

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Missed a tablet?

See page 11 of this leaflet



Summary of advice if you missed a tablet

