



Qlaira[®] is right for me



**A guide
to using Qlaira[®]
and more about
contraception**

Qlaira[®]



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Introduction

You've been prescribed Qlaira® by your doctor. This booklet will give you important information on Qlaira®.

It explains how you take Qlaira®, what happens with your body during the menstrual cycle and how the Pill works.

You will also find answers to many common questions about Qlaira® and contraception in general.

Qlaira® is a combined oral contraceptive Pill.¹

Its 26/2 dosing regimen reliably prevents pregnancy,¹ and may reduce the hormonal fluctuations related to your menstrual cycle.^{2,3}

If you have additional questions that are not covered in this booklet, read the patient information leaflet in your Qlaira® pack.



Your doctor or pharmacist will be able to answer any further questions you may have, or you can visit

www.yourlifeflow.co.za

for more information.

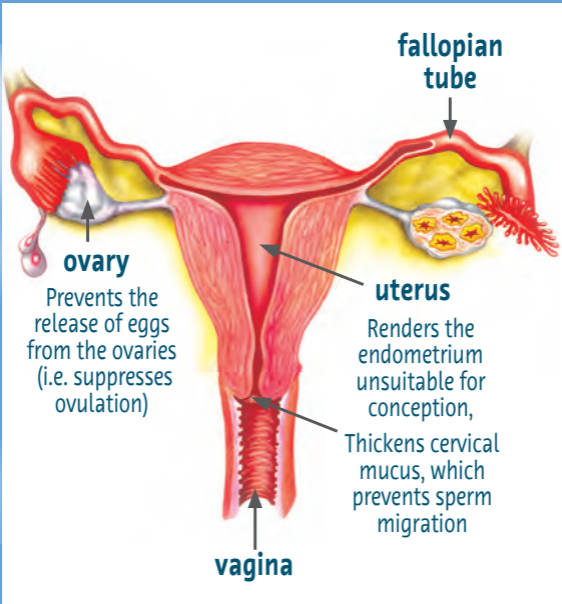
Qlaira[®]

How does combined hormonal contraception work?

The Pill is still the most popular form of contraception among adolescents,⁴ and is used by more than 100 million women worldwide.⁵

Combined hormonal contraception has 3 mechanisms of action:⁶

- Prevents the release of eggs from the ovary (i.e. inhibits ovulation)
- Decreases the ability of the sperm to penetrate through the cervix
- Thins the lining of the uterus so that it is difficult for implantation to occur



Understanding your menstrual cycle

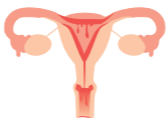
Menstruation is the shedding of the lining of the uterus (endometrium), accompanied by bleeding. It occurs in monthly cycles throughout a woman's reproductive life, except during pregnancy. Menstruation starts during puberty (at menarche) and stops permanently at menopause.⁷

- The menstrual cycle starts during puberty, typically between the ages of 10-16 years.⁸

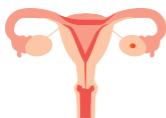
- The menstrual cycle is controlled by your female hormones estrogen and progesterone.⁷

- Hormones (mostly estrogen) stimulate the growth of the uterus lining.⁷

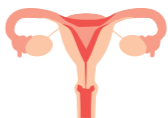
DAY 1



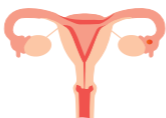
Menstruation
uterus lining is shed



Pre-ovulation
egg matures, lining grows



Post-ovulation
lining is developed fully



Ovulation
egg is released, lining grows

DAY 14

Qlaira® and your future fertility

Myth: The Pill can make you infertile.¹⁰

Fact: A large study showed that regardless of the estrogen dose, duration of use, progestogen type and parity, the Pill had no major influence on the rate of pregnancy after women stopped taking the Pill.¹⁰

Future Fertility

The Pill is a fully reversible form of contraception, which means that you can get pregnant soon after you stop taking the Pill.¹⁰ What is important to understand is that future fertility can never be proved in advance of becoming pregnant.¹¹

Myth: To preserve future fertility, you should take a regular pill-break.¹¹

Fact: Pill breaks may very well show a woman that her fertility is not impaired by an unplanned pregnancy.¹¹

What you need to know about the Pill¹²

Combined oral contraceptives:

- Do not build up in a woman's body.
- Women do not need a "rest" from taking combined hormonal contraceptives.
- Must be taken every day, whether or not a woman has had sex that day.
- Do not make women infertile.
- Do not cause birth defects or multiple births.
- Do not change women's sexual behaviour.
- Do not collect in the stomach. Instead, the Pill dissolves each day.
- Do not disrupt an existing pregnancy.

For more information visit:
[http://www.yourlifeflow.co.za/en/
your-questions/the-pill/](http://www.yourlifeflow.co.za/en/your-questions/the-pill/)

Why Qlaira®?

Over the years, the Pill has evolved. The estrogen dose has been lowered to reduce side-effects.^{5,13}

New progestogens with additional benefits to the user have been introduced. New regimens have been developed to reduce hormone withdrawal symptoms and improve the efficacy of the Pill.¹⁰ Qlaira® was the first contraceptive to introduce a new estrogen, estradiol valerate,¹⁴ for use in the combined hormonal contraceptive pill. This estrogen is similar to what your body produces naturally.¹³

Qlaira® contains 2 hormones:¹

- estrogen (17- β estradiol valerate)
- progestogen (dienogest)

Qlaira® has 26 active pills and 2 placebo pills.¹

About 17- β estradiol valerate

Ethinylestradiol has been the estrogen component in almost all combined hormonal contraceptives since the start of the Pill.¹⁴ It is only recently that another estrogen called estradiol valerate was

developed for use in contraceptives.¹³ This is 17- β estradiol, which is chemically identical to the estrogen produced by your body.¹³

About dienogest

- The progestogen in Qlaira® is dienogest¹
- The properties of dienogest include:
 - inhibiting ovulation¹⁴
 - protecting the endometrium¹⁴
 - blocking androgen receptors, resulting in an improvement in skin¹⁴
 - providing good cycle control¹⁴

About the Qlaira® 26/2 dosing regimen vs. 21/7 regimen

Menstrual symptoms are a frequent complaint during the 7 placebo tablets in traditional contraceptive pills.¹⁶ Reducing the placebo tablets to four days or, even better, two days should reduce cyclical symptoms, thereby improving a woman's physical and emotional well-being.¹⁶

The 26/2 dosing regimen of Qlaira® provides:

- the shortest hormone-free interval¹⁶
- less hormonal withdrawal symptoms, including:²



pelvic pain



headache

How to take Qlaira®¹⁵

About the Qlaira® pack

The Qlaira® pack is called a wallet, because of its folding action (like a wallet).



Important Qlaira® rules:¹⁵

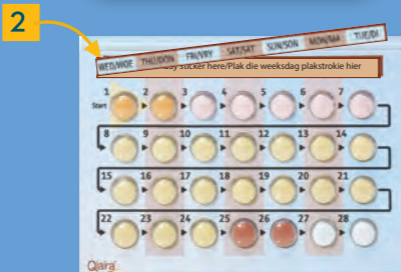
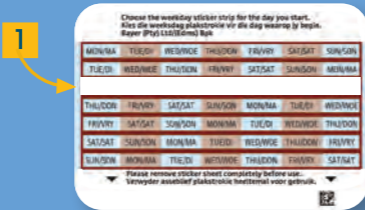


- Prepare the wallet using the correct weekday sticker.¹⁵
- Take every active pill in your Qlaira® wallet at around the same time every day.¹⁵
- Take every pill in your Qlaira® wallet (including the white inactive pills). This will make it easier for you to remember when to start your next Qlaira® wallet as there is no break between one pack and the next.¹⁵

Preparation of the wallet:¹⁵

1. There are 7 weekday sticker strips marked with the 7 days of the week.
2. Choose the weekday sticker strip that starts with the day you begin taking the pills. For example, if you start on a Wednesday, use the weekday sticker that starts with “WED/WOE”.
3. Stick the weekday sticker strip along the top of the Qlaira[®] wallet where it reads “Place weekday sticker here”, so that the first day is above the pill marked “1”.
4. There is now a day shown above every pill and you can see whether you have taken a pill on a particular day. Follow the direction of the arrows on the wallet until all 28 pills have been taken.
5. Usually, so-called withdrawal bleeding starts when you are taking the second dark red pill or the white pills and may not have finished before you start the next wallet. Some women still experience bleeding after taking the first pills 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 the inactive pills.



How to start taking Qlaira®:15

- **If you have not used a contraceptive with hormones during the previous month or ever before:**¹⁵

Start taking Qlaira® on the first day of the cycle (that is, the first day of your period).

- **After a miscarriage:**¹⁵

Follow the advice of your doctor.

- **After having a baby:**¹⁵

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 (e.g. 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”.

How to switch to Qlaira^{®1}

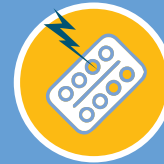
Changing from another combined hormonal contraceptive pill, or combined contraceptive vaginal ring or patch:¹

Start Qlaira[®] the day after taking the last active pill (the last pill containing the active ingredients) 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):¹

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 (e.g. a condom) during the first 9 days of Qlaira[®] use.

What to do if you miss a pill?¹



Missed more than 1 coloured pill:

- forgot to start new wallet (pack)
- forgot pills on days 3 to 9
- and had unprotected sex (without condoms) on days 3 to 9

Contact your doctor straight away

Only missed 1 pill
(more than 12 hours late)

Day 1-17



- Take the missed pill and continue taking the pills as usual (this may mean 2 pills in one day)
- Use additional contraception i.e. a barrier method (condom) for the next 9 days



Day 18-24



- Do not take the missed pill
- Start immediately with the next wallet
- Use additional contraception i.e. a barrier method (condom) for the next 9 days



Day 25-26



- Take the missed pill and continue taking the pills as usual (this may mean 2 pills in one day)
- No additional contraception necessary

Day 27-28



- Discard the missed pill and continue taking the pills as usual
- No additional contraception necessary



What about side effects of the Pill?¹⁵

Before you use Qlaira[®]:¹⁵

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.

There may be side effects from taking the Pill. Most of the side effects listed under “frequent side effects” are temporary, lasting for the first few months while your body gets used to the Pill.



**If you are concerned about side effects,
speak to your doctor or pharmacist.**

Frequent side effects ($\geq 1/100$ to $< 1/10$ women):^{1,15}

- headache
- acne
- breast pain
- breast discomfort
- heavy, irregular bleeding
- weight gain



Less frequent side effects ($\geq 1/1000$ to $< 1/100$ women):^{1,15}

- 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
- breast enlargement



Rare side effects ($\geq 1/10\ 000$ to $< 1/1000$ women):^{1,15}

- 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 or restlessness/reduced attention
- migraine with aura
- tension headache
- contact lens intolerance
- hot flushes
- low blood pressure
- painful veins
- bloating
- diarrhoea or vomiting
- golden brown pigment patches (chloasma)
- other pigmentation disorders
- allergic skin reactions
- excessive hair growth
- itching
- skin tightness
- hives
- muscle spasms
- sensation of heaviness
- vulvovaginal dryness

In addition to the side effects mentioned, the skin disorders: erythema nodosum, erythema multiforme, as well as breast discharge and hypersensitivity have occurred in women using combined hormonal contraceptives containing ethinylestradiol.¹



Not all side effects reported for Qlaira® are included in this booklet. Should your general health worsen while taking the Pill, please consult your healthcare professional for advice.



Who should not use Qlaira[®]?^{1,15}

Do not use Qlaira[®] if you are:¹⁵

- pregnant
- allergic to estradiol valerate or dienogest, or any of the other ingredients of Qlaira[®]. This may cause itching, rash or swelling.



Do not use Qlaira® if you have ever had:¹⁵

- 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 an indicator of a future heart attack (e.g. angina pectoris which causes severe chest pain) or of a stroke (e.g. 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/s or genitals
- any unexplained bleeding from the vagina

What are the risks of combined hormonal contraceptives (CHCs)?

Venous thromboembolism (VTE) with CHC use is a class-effect, and is considered a rare but serious adverse effect in users of CHCs. A class-effect means it is true for all CHCs including the Pill, the vaginal ring and the patch.¹⁷

The risk of VTE during hormonal contraceptive use is lower than during pregnancy and postpartum (period after giving birth).¹⁸

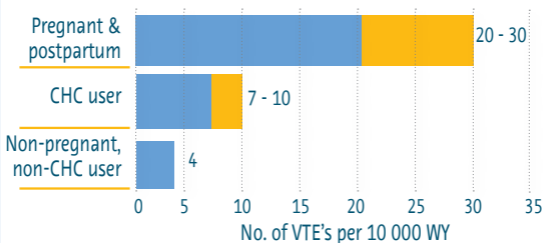
For most healthy CHC users, the benefits outweigh the risks when the contraceptive method is used correctly.¹⁸

VTE risk increases with:^{1,19}

- pregnancy
- childbirth
- major surgery/any surgery to the legs/hip or leg fracture
- major trauma
- increasing age

- smoking
- personal or family history of VTE
- inherited clotting abnormalities/
thrombophilia
- obesity (BMI of 30 kg/m² and higher)
- prolonged immobilisation
- starting combined oral contraceptive use,
or re-starting after a 4 week break²⁰
- first year of CHC use²⁰
- cancer

Risk of venous thromboembolism incidence rates per 10 000 WY



Adapted from Dinger J. 2014²¹ Heit JA. 2005²²

BMI – Body mass index
 CHC – Combined hormonal contraceptive
 VTE – Venous thromboembolism
 WY – Woman years

Signs and symptoms of a possible VTE¹⁵

- unusual cough or breathlessness
- severe pain in the chest which may reach the left arm
- 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 hearing, sense of smell, or taste
- dizziness or fainting
- weakness or numbness in any part of the body
- severe pain in the abdomen
- severe pain or swelling in either leg





Stop taking the Pill and see your doctor immediately if you notice any of these possible signs.

For more information read the patient leaflet in your Qlaira® pack.



FAQ's

What to do if:



I was sick and vomited after taking the Pill. Will the Pill still work?¹⁵

If you vomit within 3 to 4 hours of taking an active pill or you have severe diarrhoea, there is a risk that the active ingredients in the pill are not fully absorbed by the body. The situation is almost the same as forgetting to take a pill. After vomiting or diarrhoea, take a pill as soon as possible from another wallet. 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 the section “What to do if you miss a pill?”.

I have unexpected bleeding. Is this normal?¹⁵

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 pill, or the following day(s). If unexpected bleeding occurs for more than 3 months, or suddenly starts after several months speak to your doctor.

I have taken all the pills correctly, but my bleeding has not started on day 26 or the following day(s) as it is supposed to.¹⁵

If you have taken all the pills 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 pills incorrectly or if the expected bleeding does not occur during 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.

I want to stop taking Qlaira®. What should I do?¹⁵

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 contraception. If you would like to become pregnant, stop taking Qlaira® and wait for a menstrual period before starting to try and become pregnant. This will assist you to calculate the expected delivery date more easily.

I am taking the Pill as well as other medication. Does this affect the reliability of the Pill?¹⁵

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 medicine containing ketoconazole or an antibiotic 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.

Can I take Qlaira® while I am breastfeeding?¹⁵

You should not take Qlaira® while you are breastfeeding. If you require contraception while you are breastfeeding speak to your doctor first.

Does the Pill protect me from AIDS and STIs?¹⁵



The Pill (including Qlaira®) offers no protection from Human Immunodeficiency Virus (HIV), the virus that causes Acquired Immune Deficiency Syndrome (AIDS) or any other Sexually Transmitted Infection (STI).¹⁸ Always use a condom unless you are in a

faithful relationship with someone you really trust and are both sure that neither of you are carrying a STI.

Can anyone use the Pill?¹⁵

Not everyone can use the combined oral contraceptive pill. Your doctor will need to ask you about your medical history as well as your family's. It is important to advise your doctor of any illness or operations you may have had.

There are some conditions where you may not be able to take the combined oral contraceptive pill:

- if you might already be pregnant
- if you are very overweight
- if you take certain medicines
- if you suffer from migraines
- if you or a close family member have had a blood clot, or have hereditary clotting abnormalities
- if you have diabetes
- if you have severe liver disease or liver cancer
- if you or your family have had cancer of the breast/s or genital organs
- if you have undiagnosed vaginal bleeding
- if you are hypersensitive or allergic to any of the ingredients in Qlaira®

Important messages for new COC-users⁶

1. Read your patient information leaflet in the Qlaira[®] pack.
2. The Pill is only effective if you take it correctly.
3. If bleeding, like a “period” occurs (BTB), continue to take the Pill. Contact your doctor if necessary.
4. Nausea is a common symptom that may occur when you start the Pill. It usually settles as your body gets used to the Pill.
5. Never take the Pill late, even if your withdrawal bleed (period) has not stopped.
6. If you decide to stop the Pill, you must use alternative contraception to prevent pregnancy e.g. condom.
7. Vomiting and severe diarrhoea may influence the efficacy of the Pill (see FAQs on page 33).

COC – Combined oral contraceptive
STI – Sexually Transmitted Infection
HIV – Human Immunodeficiency Virus

FAQ – Frequently asked questions
BTB – Breakthrough bleeding
VTE – Venous thromboembolism

8. See a doctor immediately if you experience any of the signs and symptoms of a possible VTE (see page 31).
9. To avoid a “period” on holidays or special occasions, see your patient information leaflet in the Qlaira® pack.
10. The Pill does not provide protection against STIs and HIV.



Additional information

For more information about contraception:
Speak to your doctor or pharmacist or visit
www.yourlifenow.co.za



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References: 1. Qlaira® professional information Sept. 2011. 2. Macías G, Merki-Feld GS, Parke S, et al. Effects of a combined oral contraceptive containing oestradiol valerate/dienogest on hormone withdrawal-associated symptoms: results from the multicenter, randomised, double-blind, active-controlled HARMONY II study. *J Obstet Gynaecol* 2013;33(6):591-596. 3. Nappi RE, Serrani M, Jensen JT. Noncontraceptive benefits of the estradiol valerate / dienogest combined oral contraceptive: a review of the literature. *International Journal of Women's Health* 2014;6:711-718. 4. Nelson AL. Folates for reduction of risk of neural tube defects: using oral contraceptives as a source of folate. *Open Access Journal of Contraception* 2011;2:137-150. 5. Christin-Maitre S. History of oral contraceptive drugs and their use worldwide. *Best Practice & Research Clinical Endocrinology & Metabolism* 2013;27:3-12. 6. Guillebaud J. *Contraception Today. A pocket book for General Practitioners and nurses.* 7th Ed. 2012. 7. Brzyski RG, Knudtson J. *Menstrual Cycle.* Merck Manuals Consumer version. MSD 2016. 8. Brzyski RG, Knudtson J. *Puberty in girls.* Merck Manuals Consumer version. MSD 2016. 9. Goodman M. *Basic Medical Endocrinology (Fourth Edition).* 2009, Pages 257-275. 10. Cronin M, Schellschmidt I, Dinger J. Rate of pregnancy after using drospirenone and other progestin-containing oral contraceptives. *Obstet & Gynecol* 2009;114(3):616-622. 11. Guillebaud J. *Contraception Today.* 6th Ed. 12. WHO Family planning handbook 2018. 13. Fruzzetti F, Trémolieres F, Bitzer J. An overview of the development of combined oral contraceptives containing estradiol: focus on estradiol valerate/dienogest. *Gynecol Endocrinol* 2012;28(5):400-408. 14. Mueck AO, Seeger H, Buhling KJ. Why use of dienogest for the first contraceptive pill with estradiol? *Gynecological Endocrinology* Feb 2010;26(2):109-113. 15. Qlaira® patient information leaflet Sept. 2011. 16. Graziottin A. The shorter, the better: A review of the evidence for a shorter contraceptive hormone-free interval. *Eur J Contraception and Reprod Health Care* 2016;21:93-105. 17. Dinger JC, Heinemann LAJ, Kühl-Habich D. The safety of a drospirenone-containing oral contraceptive: final results from the European Active Surveillance study on oral contraceptives based on 142,475 women-years of observation. *Contraception* 2007;75:344-354. 18. Reid RL, Westhoff C, Mansour D, et al. Oral contraceptives and venous thromboembolism: consensus opinion from an international workshop held in Berlin, Germany in December 2009. *J Fam Plann Reprod Health Care* 2010;36(3):117-122. 19. Anderson FA, Spencer FA. Risk factors for venous thromboembolism. *Circulation* 2003;107:19-116. 20. Dinger J, Mohner S, Heinemann K. Cardiovascular risks associated with the use of drospirenone-containing combined oral contraceptives. *Contraception* 2016;93:378-385. 21. Dinger JC, Bardenheuer K, Heinemann K. Cardiovascular and general safety of a 24-day regimen of drospirenone-containing combined oral contraceptives: final results from the International Active Surveillance Study of Women Taking Oral Contraceptives. *Contraception* 2014;89:253-263. 22. Heit JA, Kobbervig CE, James AH, et al. Trends in the incidence of venous thromboembolism during pregnancy or postpartum: A 30-year population-based study. *Ann Intern Med* 2005;143(10):697-706.

[S3] Qlaira® Tablets. The 28-day pack contains 2 dark yellow tablets each containing 3 mg estradiol valerate and 5 medium red tablets each containing 2 mg estradiol valerate and 2 mg dienogest and 17 light yellow tablets each containing 2 mg estradiol valerate and 3 mg dienogest and 2 dark red tablets each containing 1 mg estradiol valerate and 2 placebo tablets. RSA Reg. No.: 43/18.8/0591. Namibia: [NS2]; Reg. No.: 13/21.8.2/0154. Mauritius Reg. No.: R9050/02/14.

For full professional information, please refer to the package insert approved by SAHPRA.