

**NATURALLY
MATCHED^{1,2}**

zoely[®]
norgestrol acetate 2.5mg
estradiol 1.5mg

From first contraception to menopause³



**This booklet is intended for patients who
have been prescribed Zoely[®]**

zoely[®]

Patient Booklet

www.zoely.co.za



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**NATURALLY
DERIVED**



What is Zoely®?

- ZOELY® is an oral contraceptive tablet (birth control 'pill') that contains small amounts of two hormones, norgestrel acetate (a progestogen) and estradiol (an oestrogen).¹
- These hormones are similar to those that are produced naturally in your body.¹
 - Estradiol or E2 is identical to the oestrogen in your body.¹
 - Norgestrel acetate or NOMAC is a pure progesterone similar to that produced in your body.¹

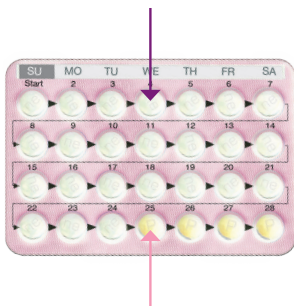


ZOELY® tablets contain the ideal combination of hormones for naturally balanced contraception.²

Each blister pack of ZOELY® contains **28 tablets:**¹

- 24 active white tablets
- 4 inactive yellow tablets

The same amount of hormones are contained in each of the 24 active white tablets.¹



4 inactive yellow tablets do not contain any hormones.¹

Zoely®'s safety and effectiveness has been thoroughly proven in the largest study performed on combined oral contraceptives (COCs). This study included 101 498 women, from 1st time users through to menopause.³

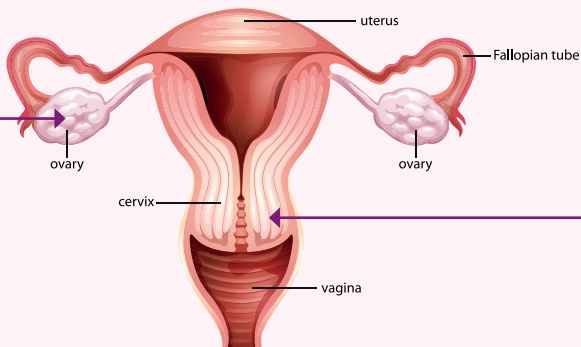
**NATURALLY
DEPENDABLE³**

How does Zoely[®] work to prevent pregnancy?

The hormones in ZOELY[®] work hand-in-hand.²

Prevents ovulation

(stops the monthly release of an egg by the ovaries).^{2,4}



Changes the mucus produced by the cervix⁴

- Thickens the cervical mucus, affecting the ability of sperm to reach the egg.⁵
- Changes the lining of the uterus making it less suitable for egg implantation.⁵

ZOELY[®] provides naturally balanced protection.²



When you have not used any hormonal contraceptive in the past month

- ZOELY® protects you from the very first pill when you start taking it on the **first** day of your menstrual period.⁶



If you start taking ZOELY® from days 2 to 5 of your menstrual period, you should use a barrier method of contraception (e.g. condoms) until you have taken the white active tablets for 7 consecutive days.⁶

- You can expect your menstrual period on day 2 to 3 after you have taken the last white tablet and it may continue after the next pack is started.⁶
- Your next pack must be started immediately after finishing the previous pack, even if your period has not finished.⁶
- Continue to take ZOELY® without any breaks irrespective of whether or not you have your menstrual period.¹

How to switch from your previous contraceptive method to Zoely®



Switching from another birth control pill containing oestrogen and progesterone

- Start ZOELY® the day after your last active tablet (of your previous oral contraceptive).⁶



Switching from a vaginal ring or transdermal patch

- Start ZOELY® on the day it is removed.⁶



Switching from a progestogen-only method such as a minipill, implant, injectable or a hormone-medicated intra-uterine device (IUD):⁶

- You may switch any day from the minipill and start ZOELY® the next day at the same time.
- Your implant or IUD may be removed any day and ZOELY® should be started on the day of its removal.
- If you have been receiving the injection, ZOELY® should be started on the day when the next injection would have been due.

If you are not sure about how to make the switch to Zoely® Speak to your healthcare provider



You are advised to use a barrier method of contraception such as a condom until you have taken the white active tablets for 7 consecutive days.⁶

If you have been using your previous contraceptive method consistently and correctly and you do not suspect you are pregnant, you may start ZOELY® immediately.⁶



NATURALLY CONSIDERATE⁷

How will Zoely[®] affect my periods?

- You can expect shorter, lighter periods while taking ZOELY[®], on average lasting 3 to 4 days.⁷



2-3 out of 10 women
may miss their
period while taking
ZOELY[®].⁷

- This is normal when taking ZOELY[®] and no reason for concern if you have not skipped any pills.⁷



Will menstrual blood build up in my uterus if I miss a period?

- No. Menstrual blood or the lining of the uterus do not build up if you do not have a withdrawal bleed while taking ZOELY®.⁸

The hormones in birth control pills cause the lining of the uterus to thin.⁸

Is it harmful if I do not have my period while taking ZOELY®?

- No, missing a period while taking a birth control pill is not harmful to your health.⁸



In fact, it is not medically necessary to have a monthly period if a woman is taking a birth control pill such as ZOELY®.⁸

- Many women would prefer to reduce scheduled withdrawal bleeds if given the choice.
- Less frequent scheduled withdrawal bleeds may be an advantage to women who suffer from painful menstrual periods.
- It may also interfere less with sporting activities and may result in less menstrual-related absence from work.
- Having fewer periods may also reduce the cost and inconvenience associated with feminine hygiene products.⁸

How will I know if I am pregnant when I miss a period?⁶



Clinical trials with ZOELY[®] have shown that you may occasionally miss your regular monthly period after Day 24.⁶

- If you have taken all the tablets correctly, and you have not vomited or had severe diarrhoea, or used other medicines, then it is very unlikely that you are pregnant. Keep taking ZOELY[®] as usual.⁶
- If you have **not** taken all the tablets correctly, or if your expected period does not happen twice in a row, you may be pregnant. Contact your doctor immediately. Do not start the next blister of ZOELY[®] until your doctor has checked that you are not pregnant.⁶



Missed
bleed

+



Missed
bleed

=



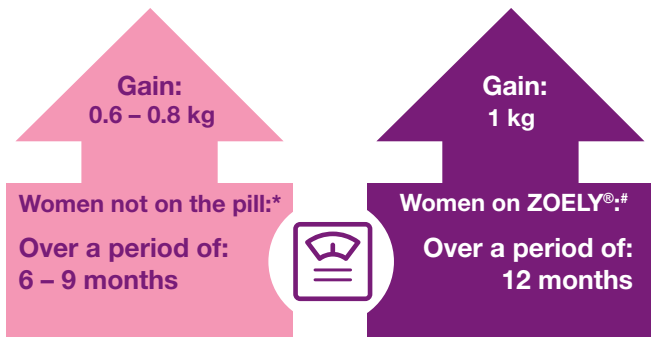
NATURALLY CONSIDERATE⁷

Will **ZOELY[®]** affect my weight?



ZOELY[®] will not affect your weight any more than women who don't use birth control pills.⁷

- One study in women **up to 50 years** of age showed similar weight results for women on ZOELY[®] and women not on the pill.⁷



^{*}18-35 years of age, average gain

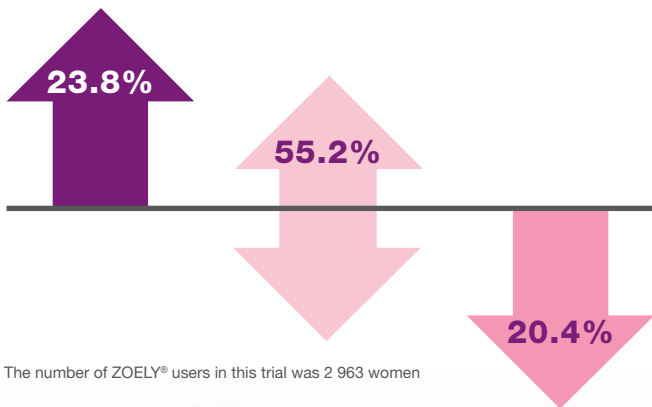
[#]18-50 years of age, increase in mean body weight, number of ZOELY[®] users in this trial was 1 591 women

- In another study in women **younger than 25 years** of age, most women reported no change in their weight after taking ZOELY® for 12 months.⁹

Weight gain

No weight gain

Weight loss



The number of ZOELY® users in this trial was 2 963 women



ZOELY® and your skin

ZOELY® does not cause acne.⁷ Most women with acne showed no signs of worsening (of their acne) while taking ZOELY®.⁷

ZOELY® and your sex life

- ZOELY® does not affect your sexual desire.¹⁰

ZOELY® on period related symptoms

ZOELY® improves related symptoms such as:¹⁰

- Headache
- Breast pain/tenderness
- Abdominal swelling and fluid retention
- Feeling down

ZOELY® respects your body^{2,7}

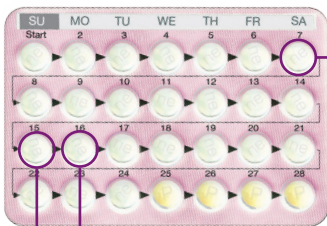
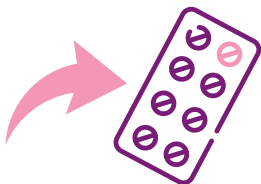
- ZOELY® is naturally balanced.²
- ZOELY® has a neutral effect on your blood pressure, blood sugar levels and cholesterol levels.^{2,4,7}

NATURALLY FORGIVING

Missed a pill?

I've missed an active white tablet.

What do I do?



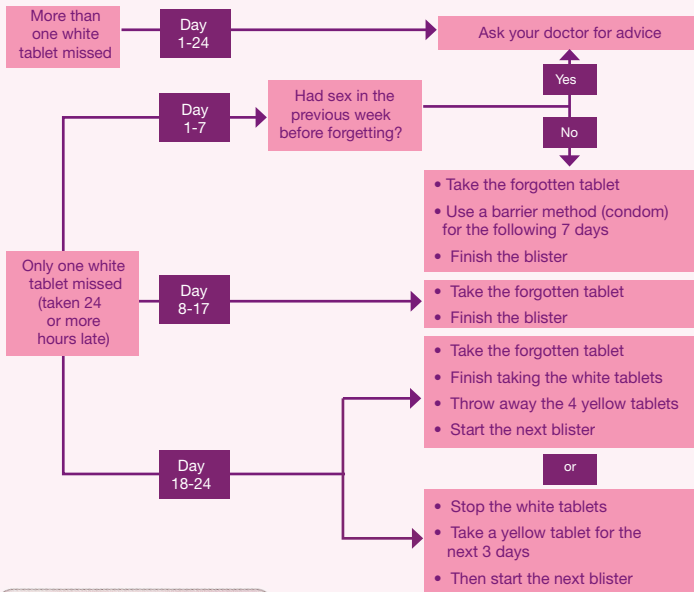
If you are less than 24 hours late in taking a white tablet:⁶

- Take the tablet as soon as you remember and take the next tablet at the usual time⁶
- Your contraceptive protection is not reduced⁶

If you are 24 hours/more than 24 hours late in taking a white tablet:⁶

- Contraceptive protection is reduced, which means you may fall pregnant⁶
- It is important to follow the rules in the section below (Management of **missed white pills**)⁶

Schedule if you are 24 hours or more late taking white pills⁶



Missed any yellow tablets?

You are still protected but you should throw away the forgotten yellow pills so you do not prolong the placebo (inactive) phase.¹

What if you cannot remember?

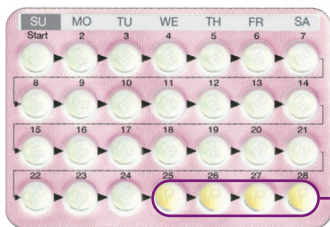
If you are not sure about the number or colour of tablets you missed, take extra precaution and use a barrier method until you have completed 7 consecutive days of taking the white active tablets.¹

Delaying your period with ZOELY®



Want to go on holiday without the hassle of your period? To delay your period:

- Start a new pack of ZOELY® after the last white tablet in your current pack.¹



Skip the yellow tablets and start with the white tablets of the next pack.¹



You may possibly experience breakthrough bleeding or spotting¹

- Once you have taken the yellow tablets of the second pack, continue taking ZOELY® as you would usually do.¹
- To shift your periods to start on another day of the week, you can shorten the number of yellow tablets you take (up to a maximum of 4 days).¹
- The shorter the interval, the higher the risk that you will not have a menstrual period and may experience breakthrough bleeding and spotting during the subsequent pack.¹

Some factors may prevent **ZOELY®** from working as effectively as it should, which may put you at risk of falling pregnant. The main factors are:



Having an upset stomach⁶

- ZOELY® may not work effectively if you have diarrhoea or you are vomiting. You will need additional protection during intercourse such as using a condom.⁶
- If you vomit 3 to 4 hours after taking a white tablet from your ZOELY® pack, that tablet should be regarded as missed and a new pill should be taken as soon as possible. The new pill should be taken within 24 hours of the usual time of tablet-taking if possible. You should then take the next pill at the usual time.⁶
- If 24 hours or more have passed since you had taken your last pill, then please follow the steps in the 'missed pill' section.⁶



Are there any medicines I shouldn't take whilst I am taking ZOELY®?

- Always tell your healthcare provider if you are taking any other medicine. This includes complementary or traditional medicines, and herbal products such as St. John's Wort.⁶
- Some medicines may stop ZOELY® from working properly. These include medicines used to treat:⁶
 - Epilepsy
 - HIV infections
 - Hepatitis C infection
 - Tuberculosis
 - Fungal infections

Please refer to the ZOELY® Patient Information Leaflet for examples of these medicines. When taking any of the above medicines you need to take extra contraceptive precautions during intercourse such as using a condom.

Speak to your healthcare provider if you are taking any other medication or need to take other medication while taking ZOELY®. They can tell you if you need to take additional contraceptive precautions (such as using condoms), and if so, for how long.⁶

What side effects can you expect with ZOELY®?

You may experience some of the following side effects especially in the first 3 months of starting ZOELY®.^{1,4}

- Headaches
- Pelvic pain
- Breast pain
- Painful periods
- Abnormal withdrawal bleeding

These side effects usually don't result in women discontinuing ZOELY®⁴

Speak to your doctor, pharmacy, or clinic nurse if you are concerned about any side effects.

Oral contraceptives, including ZOELY® do not protect against HIV/AIDS and other sexually transmitted diseases. When unsure, use a condom for protection.¹

NATURALLY REASSURING

What about the risk for blood clots?

Your doctor would have assessed your risk for the development of blood clots before prescribing ZOELY®. Women are more at risk of a blood clot forming during the first few months of using a contraceptive pill.² Studies have shown that ZOELY® may have a more favourable risk profile than older birth control pills which do not contain natural oestrogen.²



Signs of a blood clot can include:¹

- Unusual pain in one leg and/or swelling
- Sudden severe pain in the chest
- Sudden breathlessness
- Sudden onset of coughing
- Any unusual, severe, prolonged headache
- Sudden partial or complete loss of vision or double vision
- Slurred speech
- Vertigo
- Collapse with or without seizure
- Weakness or severe numbness suddenly affecting one side or one part of the body

ZOELY® respects your future needs⁴

Ready to start a family? Your fertility will return after you stop taking ZOELY®.^{4,11}



Almost 8 out of 10 women began ovulating again within one month after their last active tablet.^{4,11}





Refer to the patient information leaflet in the Zoely® pack for further details. Please discuss any concerns or queries you may have with your healthcare provider.

www.adcockingramrx.co.za

References: 1. ZOELY® 2,5 mg/1,5 mg film-coated tablets professional information (21 July 2022). 2. Chabbert-Buffet N, Jamin C, Lete I, *et al.* Missed pills: frequency, reasons, consequences and solutions. *Eur J Contracept Reprod Health Care.* 2017;22(3):165-169. doi: 10.1080/13625187.2017.1295437. 3. Reed S, Koro C, DiBello J, Becker K, Bauerfeind A, Franke C, *et al.* Unintended pregnancy in users of norgestrel acetate and 17 β -oestradiol (NOMAC-E2) compared with levonorgestrel-containing combined oral contraceptives: final results from the PRO-E2 study. *Eur J Contracept Reprod Health Care.* 2021 Dec;26(6):447-453. doi: 10.1080/13625187.2021.1988923. 4. Akintomide H, Panicker S. Norgestrel acetate/17-beta estradiol: a review of efficacy, safety, and patient acceptability. *Journal of Contraception* 2015;6: 77-86. 5. Allen RH. Combined estrogen-progestin oral contraceptives: Patient selection, counseling, and use. Available from: <https://www.uptodate.com/contents/combined-estrogen-progestin-oral-contraceptives-patient-selection-counseling-and-use>. [Cited June 2023]. 6. ZOELY® approved patient information leaflet, (21 July 2022). 7. Mansour D, Verhoeven C, Sommer W, *et al.* Efficacy and tolerability of a monophasic combined oral contraceptive containing norgestrel acetate and 17 β -oestradiol in a 24/4 regimen, in comparison to an oral contraceptive containing ethinylestradiol and drospirenone in a 21/7 regimen. *Eur J Contracept Reprod Health Care.* 2011;16:430-443. 8. Nappi RE, Kaunitz AM, Bitzer J, *et al.* Extended regimen combined oral contraception: A review of evolving concepts and acceptance by women and clinicians. *Eur J Contracept Reprod Health Care.* 2016;21(2):106-115. 9. von Stockum S, Bauerfeind A, Becker K, Franke C, Fruzzetti F, Calaf J, *et al.* NOMAC-E2 shows a better contraceptive effectiveness than LNG combined oral contraceptives in women under 25: real-world PRO-E2 study. *Gynecol Endocrinol.* 2023;39(1):2162036. doi: 10.1080/09513590.2022.2162036. 10. Cagnacci A, Bastianelli C, Neri M, *et al.* Treatment continuation and satisfaction in women using combined oral contraception with norgestrel acetate and oestradiol: a multicentre, prospective cohort study (BOLERO). *European Journal of Contraception & Reproductive Health.* 2018. 11. Duijkers I JM, Klipping C, Grob P, *et al.* Effects of a monophasic combined oral contraceptive containing norgestrel acetate and 17 β -oestradiol on ovarian function in comparison to a monophasic combined oral contraceptive containing drospirenone and ethinylestradiol. *Eur J Contracept Reprod Health Care.* 2010;15:314-32.

S3 ZOELY® 2,5 mg/1,5 mg film-coated tablets. Each tablet contains 2,5 mg norgestrel acetate and 1,5 mg estradiol (as hemihydrate). Reg. No. 45/18.8/0064. For full prescribing information refer to professional information approved by the medicines regulatory authority. Applicant & Marketed by: Adcock Ingram Limited. Co. Reg. No. 1949/034385/06. Private Bag X69, Bryanston, 2021, South Africa. Customer Care: 0860 ADCKOCK / 232625. www.adcock.com. Under licence from Theramex (Co. Reg. No. 10944626). 2023070710296431 August 2023.



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