

CURRENT APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS



PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

ZOELY™ 2,5 mg/1,5 mg film-coated tablets

White active tablets: Each tablet contains 2,5 mg noregestrol acetate and 1,5 mg estradiol (as hemihydrate).

Yellow placebo tablets: These tablets do not contain active substances.

Contains Sugar.

Each white active film-coated tablet contains 57,71 mg of lactose monohydrate.

Each yellow placebo film-coated tablet contains 61,76 mg of lactose monohydrate.

Read all of this leaflet carefully before you start using ZOELY.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ZOELY has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ZOELY is and what it is used for
2. What you need to know before you take ZOELY

3. **How to take ZOELY**
4. **Possible side effects**
5. **How to store ZOELY**
6. **Contents of the pack and other information**

1. What ZOELY is and what it is used for

ZOELY is a contraceptive pill that is used to prevent pregnancy.

When ZOELY is taken correctly (without missing active white tablets), the chance of becoming pregnant is very low.

2. What you need to know before you take ZOELY

Do not use ZOELY

In some situations **you should not use** a combined pill. Your doctor will advise you.

Tell your doctor if any of the following conditions applies to you before starting to use ZOELY. Your doctor may then advise you to use a different (non-hormonal) method of birth control.

- If you are allergic to estradiol or norgestrel acetate, or any other ingredients of ZOELY.
- If you have (or have ever had) a blood clot in a blood vessel (venous thrombosis) of your legs, lungs (pulmonary embolus) or other organs. For possible signs of a blood clot see section on **Blood clots (Thrombosis)**.
- If you have ever had a heart attack or a stroke.
- If you have (or have ever had) a condition that may be a first sign of a heart attack (such as angina pectoris which causes severe chest pain) or stroke (such as transient ischaemic attack, a slight temporary stroke).

- If you have a disease that may increase the risk of a clot in the arteries e.g.:
 - diabetes with damaged blood vessels.
 - very high blood pressure.
 - a very high level of fat in the blood (cholesterol or triglycerides).
- If you have a disorder affecting your blood clotting ability – for instance, protein C deficiency.
- If you have major surgery (e.g. an operation) and your ability to move around is limited for a long period of time (see **Blood clots (Thrombosis)**).
- If you have (had) a type of migraine called ‘migraine with aura’.
- If you have (had) inflammation of the pancreas (pancreatitis) associated with high levels of fat in your blood.
- If you have (had) severe liver disease and your liver is not yet working normally.
- If you have (had) a benign or malignant tumour in the liver.
- If you have (had), or if you may have, cancer of the breast or the genital organs.
- If you are pregnant or think you might be pregnant.

If any of these conditions appear for the first time while using ZOELY, stop taking it at once and tell your doctor. In the meantime, use a non-hormonal contraceptive. See also **General Notes** in the section below.

Warnings and Precautions

General Notes

Before you can begin taking ZOELY, 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 upon your personal situation, may also carry out some other tests.

In this leaflet, several situations are described where you should stop taking ZOELY, or where the reliability of ZOELY may be decreased. In such situations you should not have sexual intercourse 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 ZOELY alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

ZOELY does not protect you against HIV infections (AIDS) or any other sexually transmitted disease.

Tell your doctor if any of the following conditions apply to you. Also if the condition develops, or gets worse while you are using ZOELY, you must tell your doctor.

- If you have hereditary and acquired angioedema. Consult your doctor immediately if you experience symptoms of angioedema such as swollen face, lips, tongue and/or throat and/or difficulty in swallowing or hives, together with difficulty in breathing. Products containing oestrogens, such as ZOELY, may induce or worsen symptoms.
- If a close relative has or has ever had breast cancer.
- If you have epilepsy (see **Other medicines and ZOELY**).
- If you have liver disease (for instance jaundice) or gallbladder disease (for instance gallstones).
- If you have diabetes.
- If you have depression.
- If you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease).
- If you have SLE (systemic lupus erythematosus; a disease affecting your natural defence system).
- If you have HUS (haemolytic uraemic syndrome; a disorder of blood clotting causing failure of the kidneys).
- If you have sickle cell disease (an inherited disease of the red blood cells).

- If you have elevated fatty acid levels in your blood (hypertriglyceridaemia) or a positive family history for this condition (familial hypertriglyceridaemia). If so, you may be at an increased risk of developing pancreatitis (inflammation of the pancreas) when using ZOELY.
- If you have a condition that occurred for the first time or worsened during pregnancy or previous use of sex hormones e.g. hearing loss, porphyria (a disease of the blood), herpes gestationis (skin rash with vesicles during pregnancy), Sydenham's chorea (a disease of the nerves in which sudden movements of the body occur) (see **When should you contact your doctor**).
- If you have (or have ever had) chloasma yellowish-brown pigment patches, so called 'pregnancy patches', particularly on the face]. If so, avoid too much exposure to the sun or ultraviolet light.
- If you have recently given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start using ZOELY (see **Blood clots (Thrombosis)**).
- If you need an operation, or if you are not mobile for a long time (see **Blood clots (Thrombosis)**).

Blood clots (Thrombosis)

Blood clots in a vein

A blood clot in a vein (known as a 'venous thrombosis') can block the vein. This can happen in veins of the leg, the lung (a lung embolus), or any other organ.

Using any combined pill such as ZOELY increases a woman's risk of developing such clots compared with a woman not taking any combined contraceptive pill. The risk is also higher if you restart using a combined pill (the same product or a different product) after a break of 4 weeks or more.

The risk of blood clots in a vein increases:

- with increasing age.
- if one of your close relatives has had a blood clot in the leg, lung or other organ at a young age.

- if you are overweight.
- if you must have an operation, or if you are not mobile for a long time because of an injury or illness, or you have your leg in a plaster cast. If this applies to you, it is important to tell your doctor that you are using ZOELY, as the treatment may have to be stopped. Your doctor may tell you to stop using your hormonal contraception several weeks before surgery or while you are less mobile. Your doctor will also tell you when you can start using ZOELY again after you are able to move around (see **Do not use ZOELY**).
- if you smoke.
- if you gave birth less than a few weeks ago.

Blood clots in an artery

A blood clot in an artery can cause serious problems. For example, a blood clot in an artery in the heart causes a heart attack, or in the brain causes a stroke.

The risk of a blood clot in an artery increases:

- with increasing age.
- **if you smoke.**

When using a hormonal contraceptive like ZOELY you are strongly advised to stop smoking, especially if you are older than 35 years:

- if you are overweight.
- if you have high blood pressure.
- if a close relative has had a heart attack or stroke at a young age.
- if you have a high level of fat in your blood (cholesterol or triglycerides).
- if you get migraines.
- if you have a problem with your heart (valve disorder, disturbance of the rhythm).

Symptoms of blood clots

Stop taking tablets and see your doctor immediately if you notice possible signs of a blood clot, such as:

- an unusual sudden cough.
- severe pain in the chest which may reach the left arm.
- breathlessness.
- any unusual, severe, or long-lasting headache or worsening of migraine.
- 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 or swelling in either of your legs.

Following a blood clot, recovery is not always complete. Permanent disabilities may occur or the blood clot may even be fatal.

Directly after giving birth, women are at an increased risk of blood clots so you should ask your doctor how soon after delivery you can start using ZOELY.

Cancer

In studies with the combined Pill breast cancer has been found slightly more often in women using combined pills such as ZOELY, but it is not known whether this is caused by the treatment itself. The

increased occurrence of breast cancer becomes gradually less after stopping the combined pill, so that 10 years after stopping the extra risk has gone.

In the additional study that included both oral and non-oral hormonal contraceptive users, the occurrence of breast cancer was reported to increase the longer the women used the contraceptive. The difference in the reported risk of breast cancer between women who have never used the contraceptive and those who had used the contraceptive was small: 13 additional cases of breast cancer per 100,000 womenyears.

It is important to regularly check your breasts and you should contact your doctor if you feel any lump. You should also tell your doctor if a close relative has, or ever had breast cancer (see **Warnings and Precautions**).

Benign (non-cancerous) liver tumours, and in even fewer cases malignant (cancerous) liver tumours have been reported in pill users. Contact your doctor if you have unusual severe abdominal pain.

Cervical cancer has been reported to occur more often in women using combined oral contraceptives such as ZOELY for a long time.

When should you contact your doctor?

Regular check-ups

When you are using ZOELY, your doctor will tell you to return for regular check-ups. You should usually have a check-up every year.

Important information about some of the ingredients of ZOELY

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

Contact your doctor as soon as possible

- If you notice any changes in your own health, especially involving any of the items mentioned in this leaflet (see **Do not use ZOELY** and **Warnings and Precautions**; do not forget about the changes in the health of your immediate family).
- If you feel a lump in your breast.
- If you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or skin hives together with difficulty breathing.
- If you are going to use other medicines (see **Other medicines and ZOELY**).
- If your ability to move around is limited for a long period of time or you are to have surgery (tell your doctor at least 4 weeks in advance).
- If you have unusual, heavy vaginal bleeding.
- If you forgot one or more tablets in the first week of the blister and had unprotected intercourse in the 7 days before (see **If you forget to take ZOELY tablets**).
- If you have severe diarrhoea.
- If you miss periods and suspect you may be pregnant (do not start the next blister until your doctor tells you, see **If you have missed one or more periods**).

Stop taking tablets and contact your doctor immediately if you notice possible signs of a blood clot. The symptoms are described in Blood clots (Thrombosis).

Other medicines and ZOELY

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines). They can tell you if you need to take additional contraceptive precautions (barrier method) and, if so, for how long.

Some medicines may cause particular problems when you are using combined hormonal contraceptives, such as ZOELY.

- There are medicines that can make ZOELY less effective in preventing pregnancy, or can cause unexpected bleeding. These include medicines used to treat:
 - epilepsy (e.g. primidone, phenytoin, phenobarbital, carbamazepine, oxcarbamazepine, topiramate, felbamate).
 - HIV infections (e.g. ritonavir, nevirapine, nelfinavir, efavirenz).
 - Hepatitis C virus infection (e.g. boceprevir, telaprevir).
 - tuberculosis (e.g. rifampicin).
 - fungal infections (e.g. griseofulvin).
 - high blood pressure in the blood vessels in the lungs (bosentan).
 - the herbal product St. John's wort may also stop ZOELY from working properly. If you want to use herbal products containing St. John's wort while you are already using ZOELY you should consult your doctor first.
- If you are taking medicines or herbal products that might make ZOELY less effective, a barrier contraceptive method should ~~also~~ be used in addition to ZOELY. Since the effect of another medicine on ZOELY may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive method for that long.
- Some medicines can increase the levels of the active substances of ZOELY in the blood. Tell your doctor if you are using anti-fungal medicines such as ketoconazole or itraconazole.

- ZOELY may also interfere with the working of other medicines such as ciclosporin and the anti-epileptic medicine, lamotrigine.
- The HCV combination medicine regimen ombitasvir/paritaprevir/ritonavir with or without dasabuvir as well as regimen glecaprevir/pibrentasvir may cause increases in liver function blood test results (increase in ALT liver enzyme) in women using CHCs containing ethinylestradiol. ZOELY contains estradiol instead of ethinylestradiol. It is not known whether an increase in ALT liver enzyme can occur when using ZOELY with this HCV combination medicine regimen. Your doctor will advise you.

Use of ZOELY in pregnancy and breastfeeding

Pregnancy

ZOELY must not be used by women who are pregnant, or who think they may be pregnant. If you get pregnant while using ZOELY you should stop using ZOELY and contact your doctor.

Breastfeeding

You should not use ZOELY if you are breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professionals for advice before taking ZOELY.

Driving and using machinery

ZOELY is unlikely to affect your ability to drive or use machines.

Laboratory tests

If you are having any blood or urine tests, tell your doctor that you are using ZOELY as it may affect the results of some tests.

3. How to take ZOELY

When and how to take the tablets

The ZOELY blister contains 28 tablets: 24 white tablets with the active substances (number 1 to 24) and 4 yellow tablets without active substances (number 25 to 28).

Each time you start a new blister of ZOELY, take the number 1 active white tablet in the left-hand top corner (see 'Start'). Choose from the 7 stickers with day indicators the one in the grey column that begins with your starting day. For example, if you start on a Wednesday, use the day label sticker that starts with 'WED'. Stick it on the blister, just above the row of active white tablets where it reads 'Place day label here'. This allows you to check whether you took your daily tablet.

Take each day 1 tablet at about the same time, with some water. Follow the direction of the arrows on the blister, so use the active white tablets first and then the yellow placebo tablets.

Your period will start during the 4 days that you use the yellow placebo tablets (so-called withdrawal bleeding). Usually it will start 2 to 3 days after the last active white tablet and may not have finished before the next blister is started.

Start taking your next blister immediately after the last yellow tablet, even if your period has not finished. This means that you will always start a new blister on the same day of the week, and also that you have your period on approximately the same days, each month.

Some users may not have their period every month during the intake of the yellow tablets. If you have taken ZOELY every day according to these directions, it is unlikely that you are pregnant (see **If you have missed one or more periods**).

Starting your first pack of ZOELY

When no hormonal contraceptive has been used in the past month

Starting taking ZOELY on the first day of your cycle (i.e. the first day of your menstrual bleeding). ZOELY will work immediately. You do not need to use an additional contraceptive method.

You may also start on days 2 to 5 of your cycle, but if you do, make sure you also use an additional contraceptive method (barrier method) for the first 7 days of tablet-taking in the first cycle.

When changing from another combined hormonal contraceptive (combined oral contraceptive pill (COC), vaginal ring, or transdermal patch)

You can start taking ZOELY the day after you have taken the last tablet from your present pill blister (this means no tablet-free break). If your present pill blister also contains inactive (placebo) tablets you can start ZOELY on the day after taking the last **active** tablet (if you are not sure which tablet this is, ask your doctor or pharmacist). You can also start later, but never later than the day following the tablet-free break of your present pill (or the day after the last inactive tablet of your present pill).

In case you use a vaginal ring or transdermal patch, it is best to start using ZOELY on the day you remove the ring or patch. You can also start, at the latest, on the day you would have started using the next ring or patch.

If you have used the pill, patch or ring consistently and correctly and if you are sure that you are not pregnant, you can also stop taking the pill or remove the ring or patch on any day and start using ZOELY immediately.

If you follow these instructions, it is not necessary to use an additional contraceptive method.

When changing from a progestogen-only pill (minipill)

You can stop taking the minipill any day and start taking ZOELY the next day, at the same time. But if you are having intercourse, make sure you also use an additional contraceptive method (barrier method) for the first 7 days that you are taking ZOELY.

When changing from a progestogen-only injectable, implant or hormone-medicated intra-uterine system (IUS)

Start taking ZOELY when your next injection is due or on the day your implant or IUS is removed. But if you are having intercourse, make sure you also use an additional contraceptive method (barrier method) for the first 7 days that you are taking ZOELY.

After having a baby

You can start ZOELY between 21 and 28 days after having a baby. If you start later than day 28, use an additional contraceptive method (barrier method) during the first 7 days of ZOELY use. If, after having a baby, you have had sex before starting ZOELY, be sure that you are not pregnant or wait until the next menstrual period. If you want to start ZOELY after having a baby and are breastfeeding, see **Use of ZOELY in Pregnancy and Breastfeeding**.

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

After a miscarriage or an abortion

Your doctor will advise you.

If you take more ZOELY than you should (overdose)

There have been no reports of serious harmful effects from taking too many ZOELY Tablets at one time. If you have taken several tablets at a time, you may have nausea, vomiting or vaginal bleeding. If you discover that a child has taken ZOELY, ask your doctor for advice.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ZOELY

The following advice only refers to missed **active white** tablets

- If you are **less than 24 hours late** in taking a tablet, the reliability of the pill is maintained. Take the tablet as soon as you remember and take the next tablets at the usual time.
- If you are **24 or more hours late** in taking any tablet, the reliability of the pill may be reduced. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased. There is a particularly high risk of becoming pregnant if you miss active **white** tablets at the beginning or at the end of the blister. Therefore you should follow the rules given below.

Day 1 to 7 active white tablet intake (see picture and schedule)

Take the last active white missed tablet as soon as you remember (even if this means taking 2 tablets at the same time) and take the next tablets at the usual time. However, use a barrier method such as a condom as an extra precaution until you have taken your tablets correctly for 7 days in a row.

If you had sexual intercourse in the week before missing the tablets, there is a possibility of becoming or being pregnant. So contact your doctor immediately.

Day 8 to 17 active white tablet intake (see picture and schedule)

Take the last missed tablet as soon as you remember (even if this means taking 2 tablets at the same time) and take the next tablets at the usual time. If you have taken your tablets correctly in the 7 days prior to the missed tablet, the protection against pregnancy is not reduced, and you do not need to use extra precautions. However, if you have missed more than 1 tablet, use a barrier method such as a condom as an extra precaution until you have taken your tablets correctly for 7 days in a row.

Day 18 to 24 active white tablet intake (see picture and schedule)

There is a particularly high risk of becoming pregnant if you miss active white tablets close to the yellow placebo tablet interval. By adjusting your intake schedule this higher risk can be prevented.

The following two options can be followed. You do not need to use extra precautions if you have taken your tablets correctly in the 7 days prior to the missed tablet. If this is not the case, you should follow the first of these two options and use a barrier method such as a condom as an extra precaution until you have taken your tablets correctly for 7 days in a row.

Option 1

Take the last missed tablet as soon as you remember (even if this means taking 2 tablets at the same time) and take the next tablets at the usual time. Start the next blister as soon as the active white tablets in the current blister are finished, so **skip the yellow placebo tablets**. You may not have your period until you take the yellow placebo tablets at the end of the second blister, but you may have spotting (drops or flecks of blood) or breakthrough bleeding while taking the white active tablets.

Option 2

Stop taking the active white tablets and start taking the placebo yellow tablets so that the total number of placebo plus missed active tablets is not more than 4. For example, if you missed one active white tablet, you should take 3 days of the placebo yellow tablets; if you missed 3 active white tablets, you should take only 1 day of the placebo yellow tablets. At the end of the placebo tablet interval, start the next blister.

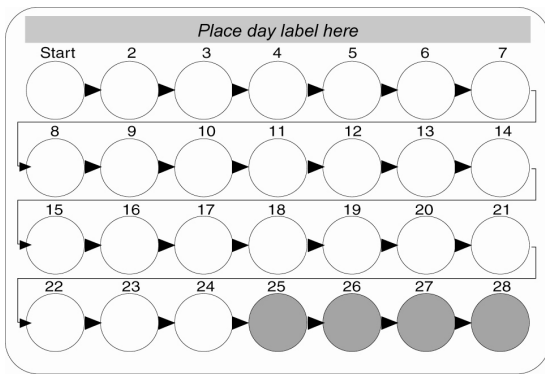
If you cannot remember how many active white tablets you have missed, follow the first option, use a barrier method, such as a condom as an extra precaution until you have taken your tablets correctly for 7 days in a row, and contact your doctor (as you may not have been protected from becoming pregnant).

If you have forgotten to take active white tablets in a blister, and you do not have the expected monthly period while taking the yellow placebo tablets from the same blister, you may be pregnant. Consult your doctor before you start with the next blister.

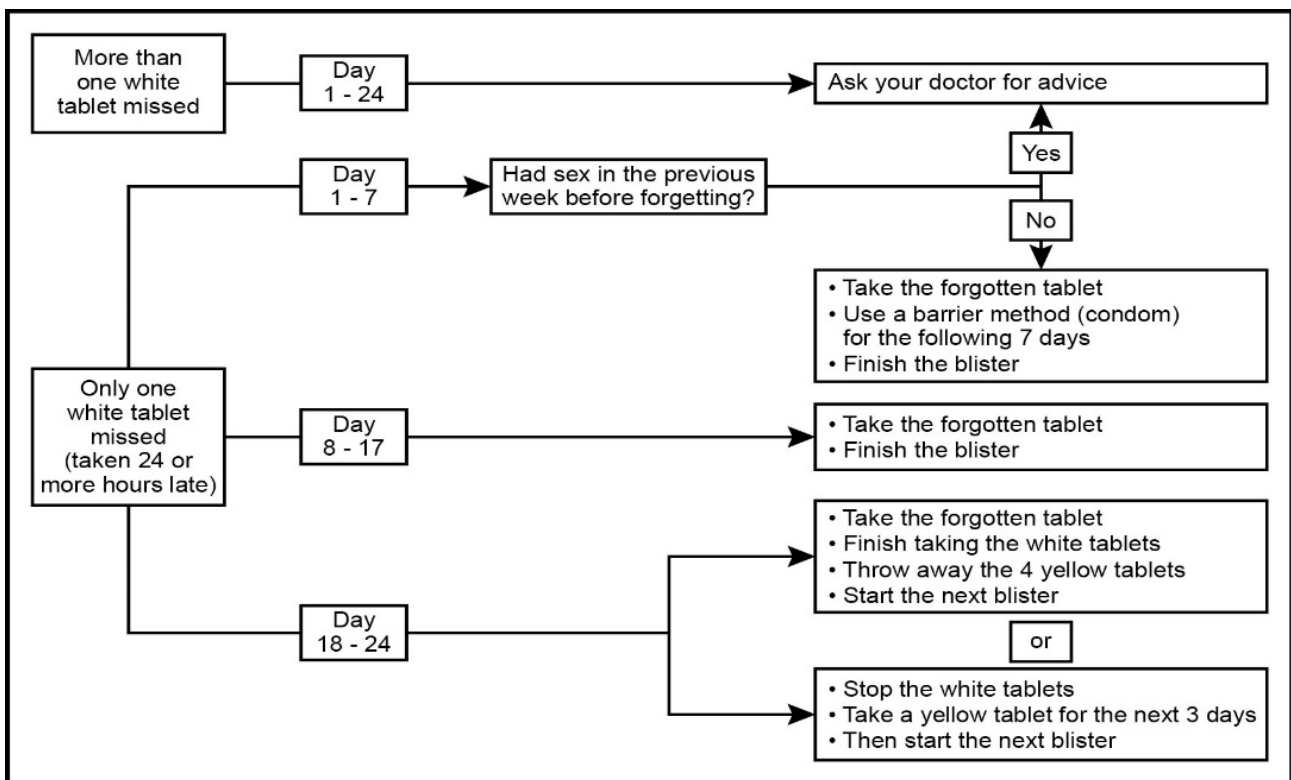
Yellow placebo tablets missed

The last 4 yellow tablets of the fourth row are placebo tablets which do not contain active substances. If you forgot to take one of these tablets the reliability of ZOELY is maintained. Throw away the yellow placebo tablet(s) you missed and continue taking the next tablets at the usual time.

Picture



Schedule: if you are 24 or more hours late taking white tablets



If you vomit or have severe diarrhoea

If you vomit within 3 to 4 hours of taking an active white tablet, or you have severe diarrhoea, the active ingredients of your ZOELY tablet may not have been completely absorbed into your body. The situation is similar to if you forget an active white tablet. After vomiting or diarrhoea, you must take it within 24 hours of when you usually take your pill. Take the next tablet at the usual time. If this is not possible or 24 or more

hours have passed, you should follow the advice given under **If you forget to take ZOELY**. If you have severe diarrhoea, please contact your doctor.

The yellow tablets are placebo tablets which do not contain active substances. If you vomit or have severe diarrhoea within 3 to 4 hours of taking a yellow tablet, the reliability of ZOELY is maintained.

If you want to delay your period

You can delay your period if you continue with the active white tablets in your next blister of ZOELY immediately after finishing the active white tablets in your current blister.

You can continue with this blister as long as you wish, until this blister is empty. When you wish your period to begin, just stop tablet-taking. While using the second blister you may have some spotting (drops or flecks of blood) or breakthrough bleeding on the active tablet-taking days. Start with your next blister after the usual 4-day placebo tablet interval.

If you want to change the starting day of your period

If you take your tablets correctly, your period will start on about the same day every month. If you want to change the day it starts, you can make the placebo tablet interval shorter (but never longer!).

For example, if your period usually begins on a Friday, you can change this to a Tuesday (3 days earlier) from next month onwards. Simply start your next blister 3 days earlier than usual.

If you make a placebo tablet interval very short (for example 3 days or less), you may not have your period until you take the yellow placebo tablets at the end of the second blister. You may however have some spotting (drops or flecks of blood) or breakthrough bleeding during the use of the active white tablets in the next blister.

If you have unexpected bleeding

For the first few months, you can have some breakthrough bleeding or spotting between your periods. You may need to use sanitary protection, but keep taking your tablets as usual. Breakthrough bleeding or spotting usually stops once your body has adjusted to the pill (usually after about 3 months). If bleeding continues, becomes heavy or starts again, contact your doctor.

If you missed one or more periods

Clinical trials with ZOELY have shown that you may occasionally miss your regular monthly period after Day 24.

- 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. See **If you vomit or have severe diarrhoea** or **Other medicines and ZOELY**.
- 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.

If you want to stop taking ZOELY

You can stop taking ZOELY at any time you want. If you do not want to become pregnant, first ask your doctor about other methods of birth control.

If you stop taking ZOELY because you want to get pregnant, you are recommended to wait until you have had a natural period before trying to conceive. This helps you to determine when the baby will be due.

4. Possible side effects

ZOELY can cause side effects.

Contact your doctor if you notice any unwanted effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by the pill.

Serious side effects seen with the pill, as well as the related symptoms, are described in section **Blood clots (Thrombosis)** and **Cancer**.

The following side effects have been reported in users of ZOELY, but the frequency cannot be estimated from the available data: blood clot in the vein, blood clot in an artery, allergic (hypersensitivity) reactions.

If any of the following happens, stop taking ZOELY and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the face, tongue and/or throat and/or difficulty swallowing or hives, together with difficulty breathing.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ZOELY. You may need urgent medical attention or hospitalisation.

The following side effects have been linked with the use of ZOELY:

Frequent

- Acne.
- Changes in the menstrual cycle (e.g. absence of menstruation or breakthrough bleeding or spotting).

- Decreased interest in sex, depression/depressed mood, mood changes, suicidal thoughts/behaviour and suicide.
- Headache or migraine.
- Feeling sick (nausea).
- Heavy menstrual periods, breast pain, pelvic pain.
- Weight gain.

Less frequent

- Fluid retention (oedema).
- Hot flushes.
- Swollen abdomen.
- Increased sweating, hair loss, itching, dry skin, oily skin.
- Heaviness in limbs.
- Regular but scanty periods, larger breasts, breast lump, milk production while not pregnant, premenstrual syndrome (symptoms may include breast swelling or tenderness, bloating, cramps, low back pain, depression, irritability), pain during intercourse, dryness in the vagina or vulva, spasm of the uterus.
- Irritability.
- Increased liver enzymes.
- Changes in appetite.
- Increased interest in sex.
- Disturbance in attention.
- Dry eye, contact lens intolerance.
- Dry mouth.
- Golden brown pigment patches, mostly in the face, excessive hair growth.

- Vaginal smell, discomfort in the vagina or vulva.

Further information on the possible side effect changes to menstrual periods (e.g. absence or irregular) during the use of ZOELY is described in section **When and how to take the tablets, If you have unexpected bleeding and If you have missed one or more periods**).

Not all side effects reported for ZOELY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Reporting of side effects

You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of ZOELY.

5. How to store ZOELY

Store all medicines out of reach of children.

Do not use ZOELY after the expiry date which is stated on the carton. The expiry date refers to the last day of the indicated month.

Store at or below 30 °C.

Do not remove tablets from blister until required for use.

Medicines should not be disposed of via waste water or household water. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What ZOELY contains

The active substances are:

In the active white tablets: Nomegestrol acetate 2,5 mg and estradiol (as hemihydrate) 1,5 mg.

In the yellow placebo tablets: No active substances.

The other ingredients are:

Tablet core (active white and yellow placebo tablets): Lactose monohydrate, microcrystalline cellulose, crospovidone, talc, magnesium stearate, silica colloidal anhydrous.

Contains lactose monohydrate.

Tablet coating (active white tablets): Polyvinyl alcohol, titanium dioxide, macrogol, talc.

Tablet coating (yellow placebo tablets): Polyvinyl alcohol, titanium dioxide, macrogol, talc, iron oxide yellow and iron oxide black.

All 24 white tablets are active tablets that contain a small amount of two different female hormones. These are nomegestrol acetate (a progestogen) and estradiol (the natural oestrogen).

The 4 yellow tablets do not contain hormones and are called placebo tablets.

Contraceptive pills like ZOELY, are called "combined contraceptive pills".

What ZOELY looks like and contents of the pack

The active tablets are white, round and 5,5 mm in diameter. They are coded 'ne' on both sides.

The placebo tablets are yellow, round and 5,5 mm in diameter. They are coded 'p' on both sides.

ZOELY Tablets are packed in PVC/aluminium blister (transparent PVC thermoforming film with aluminium lidding foil), packed in a printed cardboard box. Packed in pack sizes of 28 tablets.

Holder of certificate of registration

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

South Africa

This leaflet was last revised

21 July 2022

REGISTRATION NUMBER

45/18.8/0064