SCHEDULING STATUS: S3

ZOELY® 2,5 mg/1,5 mg film-coated tablets
Nomegestrol acetate / Estradiol
Contains sugar (lactose monohydrate 57,71 mg per white active tablet and 61,76 mg per yellow placebo tablet)

Read all of this leaflet carefully before you start taking 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 take ZOELY
You must not take ZOELY if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor. Your doctor will discuss with you what other form of birth control would be more appropriate.
- If you are allergic to estradiol or nomegestrol acetate, or any other ingredients of ZOELY (listed in section 6).
- If you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs. For possible signs of a blood clot see section 'Blood clots'.
- If you have a disorder affecting your blood clotting - for instance, protein C deficiency, protein S deficiency, antithrombin – III deficiency, Factor V Leiden or antiphospholipid antibodies.
- If you need an operation or if you are off your feet for a long time (see section 'Blood clots').
- If you have ever had a heart attack or a stroke.
- If you have ever had angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA, temporary stroke symptoms).
- 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)
  - a condition known as hyperhomocysteinaemia.
- If you have (or have ever had) a type of migraine called 'migraine with aura'.
- If you have (or have ever had) inflammation of the pancreas (pancreatitis) associated with high levels of fat in your blood.
- If you have (or have ever had) severe liver disease and your liver is not yet working normally.
- If you have (or have ever had) a benign or malignant tumour in the liver.

- If you have ever had, or if you may have, cancer of the breast or the genital organs.
- If you have meningioma or have ever been diagnosed with a meningioma (a generally benign tumour of the tissue layer between the brain and the skull).
- If you have any unexplained bleeding from the vagina.
- 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 section 2 above.

Warnings and precautions

General notes
Before you start taking ZOELY you should read the information on blood clots (thrombosis) in section 2. It is particularly important to read the symptoms of a blood clot – see section 2 'Blood clots'.

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.

Important things to know about combined hormonal contraceptives (CHCs):
- They are one of the most reliable reversible methods of contraception if used correctly.
- They slightly increase the risk of having a blood clot in the veins and arteries, especially in the first year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks.
- Please be alert and see your doctor if you think you may have symptoms of a blood clot (see section 2 'Blood clots').

Talk to your doctor or pharmacist before taking ZOELY.

When should you contact your doctor?
Seek urgent medical attention:
- If you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e., deep vein thrombosis), a blood clot in the lung (i.e., pulmonary embolism), a heart attack or a stroke (see 'Blood clots' section below). For a description of the symptoms of these serious side effects please go to 'How to recognise a blood clot'.
- If you notice any changes in your own health, especially involving any of the items mentioned in this leaflet (see also in section 2 'Do not take ZOELY'; 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 hives together with difficulty breathing.
- If you are going to use other medicines (see also in section 2 'Other medicines and ZOELY').
- If you are to be immobilised or are to have surgery (tell your doctor at least four weeks in

advance).
- If you have unusual, heavy vaginal bleeding.
- If you forgot one or more tablets in the first week of the blister pack and had unprotected sex in the seven days before (see also in section 3 'If you forget to take ZOELY').
- If you have severe diarrhoea or experience severe vomiting.
- If you miss periods and suspect you may be pregnant (do not start the next blister pack until your doctor tells you, see also in section 3 'If you have missed one or more periods').

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.
If the condition develops, or gets worse while you are taking 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 systemic lupus erythematosus (SLE; a disease affecting your natural defence system).
- If you have haemolytic uraemic syndrome (HUS; 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 taking ZOELY.
- If you have a condition that occurred for the first time or worsened during pregnancy or previous use of female 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).
- 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 just given birth, you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking ZOELY (see 'Blood clots').
- If you need an operation, or if you are off your feet for a long time (see 'Blood clots').
- If you have an inflammation in the veins under the skin (superficial thrombophlebitis).
- If you have varicose veins.

BLOOD CLOTS
Using a combined hormonal contraceptive such as ZOELY increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block blood vessels and cause serious problems.

Blood clots can develop:
- in veins (referred to as a 'venous thrombosis', 'venous thromboembolism' or VTE)

- in the arteries (referred to as an 'arterial thrombosis', 'arterial thromboembolism' or ATE).

Recovery from blood clots is not always complete. There may be serious lasting effects or they may be fatal.

It is important to remember that the overall risk of a harmful blood clot due to ZOELY is small.

HOW TO RECOGNISE A BLOOD CLOT

Seek urgent medical attention if you notice any of the following signs or symptoms.

Are you experiencing any of these signs?	**What are you possibly suffering from?**
• swelling of one leg or along a vein in the leg or foot especially when accompanied by: - pain or tenderness in the leg which may be felt only when standing or walking - increased warmth in the affected leg - change in colour of the skin on the leg e.g., turning pale, red or blue	Deep vein thrombosis
• sudden unexplained breathlessness or rapid breathing • sudden cough without an obvious cause, which may bring up blood • sharp chest pain which may increase with deep breathing • severe light headedness or dizziness • rapid or irregular heartbeat • severe pain in your stomach If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g., a 'common cold').	Pulmonary embolism
Symptoms most commonly occur in one eye: • immediate loss of vision or • painless blurring of vision which can progress to loss of vision	Retinal vein thrombosis (blood clot in the eye)
• chest pain, discomfort, pressure, heaviness • sensation of squeezing or fullness in the chest, arm or below the breastbone • fullness, indigestion or choking feeling • upper body discomfort radiating to the back, jaw, throat, arm and stomach • sweating, nausea, vomiting or dizziness • extreme weakness, anxiety, or shortness of breath • rapid or irregular heartbeats	Heart attack
• sudden weakness or numbness of the face, arm or leg, especially on one side of the body • sudden confusion, trouble speaking or understanding • sudden trouble seeing in one or both eyes • sudden trouble walking, dizziness, loss of balance or coordination • sudden, severe or prolonged headache with no known cause	Stroke

• loss of consciousness or fainting with or without seizure Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.	
• swelling and slight blue discolouration of an extremity • severe pain in your stomach (acute abdomen)	Blood clots blocking other blood vessels

BLOOD CLOTS IN A VEIN

What can happen if a blood clot forms in a vein?

- The use of combined hormonal contraceptives has been connected with an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare. Most frequently, they occur in the first year of use of a combined hormonal contraceptive.
- If a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung, it can cause a pulmonary embolism.
- Very rarely a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

When is the risk of developing a blood clot in a vein highest?

The risk of developing a blood clot in a vein is highest during the first year of taking a combined hormonal contraceptive for the first time. The risk may also be higher if you restart taking a combined hormonal contraceptive (the same product or a different product) after a break of 4 weeks or more.

After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive.

When you stop ZOELY your risk of a blood clot returns to normal within a few weeks.

What is the risk of developing a blood clot?

The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you are taking.

The overall risk of a blood clot in the leg or lung (DVT or PE) with ZOELY is small.

- Out of 10 000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.
- Out of 10 000 women who are using a combined hormonal contraceptive that contains levonorgestrel, norethisterone, or norgestimate, about 5-7 will develop a blood clot in a year.
- The risk of a blood clot with ZOELY compares to the risk with a combined hormonal contraceptive that contains levonorgestrel.
- The risk of having a blood clot will vary according to your personal medical history (see 'Factors that increase your risk of a blood clot' below).

	Risk of developing a blood clot in a year
Women who are **not using** a combined hormonal pill and are not pregnant	About 2 out of 10 000 women
Women using a combined hormonal contraceptive pill containing **levonorgestrel, norethisterone or norgestimate**	About 5-7 out of 10 000 women
Women using ZOELY	About the same as with other combined hormonal contraceptives including

	contraceptives containing levonorgestrel

Factors that increase your risk of a blood clot in a vein
The risk of a blood clot with ZOELY is small but some conditions will increase the risk. Your risk is higher:
- if you are very overweight (body mass index or BMI over 30 kg/m^2).
- if one of your close relatives has had a blood clot in the leg, lung or other organ at a young age (e.g., below the age of about 50 years). In this case you could have a hereditary blood clotting disorder.
- if you must have an operation, or if you are off your feet 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').
- as you get older (particularly above about 35 years)
- if you gave birth less than a few weeks ago.

The risk of developing a blood clot increases the more conditions you have.

Air travel (for longer than 4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.
It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that ZOELY needs to be stopped.

If any of the above conditions change while you are using ZOELY, for example a close family member has a thrombosis for no known reason or you gain a lot of weight, tell your doctor.

BLOOD CLOTS IN AN ARTERY
What can happen if a blood clot forms in an artery?
Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

Factors that increase your risk of a blood clot in an artery
It is important to note that the risk of a heart attack or stroke from using ZOELY is very small but can increase:
- with increasing age (beyond about 35 years).
- if you smoke. When using a combined hormonal contraceptive like ZOELY you are strongly advised to stop smoking. If you are unable to stop smoking and are older than 35 years your doctor may advise you to use a different type of contraceptive.
- 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 (less than about 50 years). In this case you could also have a higher risk of having a heart attack or stroke.
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides).
- if you get migraines, especially migraines with aura.
- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation).
- if you have diabetes.

If you have more than one of these conditions or if any of them are particularly severe, the risk of developing a blood clot may be increased even more.

If any of the above conditions change while you are taking ZOELY, for example, you start smoking, a close family member experiences a thrombosis for no known reason or you gain a lot of weight, tell your doctor.

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.

Meningiomas
Use of nomegestrol acetate, as contained in ZOELY, has been linked to the development of a generally benign tumours of the tissue layer between the brain and the skull (meningioma). The risk increases especially when you use it at high doses for longer duration (several years). If you are diagnosed with meningioma, your doctor will stop your treatment with ZOELY (see section ‘Do not use ZOELY’). If you notice any symptoms such as changes in vision (e.g., seeing double or blurriness), hearing loss or ringing in the ears, loss of smell, headaches that worsen with time, memory loss, seizures, weakness in your arms or legs, you must tell your doctor straightaway.

Psychiatric disorders
Some women using hormonal contraceptives including ZOELY have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

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.

Children and adolescents
No data on efficacy and safety are available in adolescents below 18 years.

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 (HCV) 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 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.

Pregnancy and breastfeeding
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.

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.

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.

3. How to take ZOELY
Do not share medicines prescribed for you with any other person.
Always take ZOELY exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you ae not sure.

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.

Each day take 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
Start 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 '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 you 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.

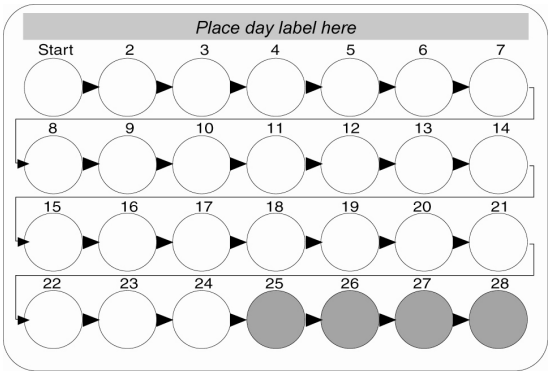
Option 2
Stop taking the active white tablets and start taking the placebo yellow tablets so that the total number of placebo plus missed active tablets is not more than 4. For example, if you missed one active white tablet, you should take 3 days of the placebo yellow tablets; if you missed 3 active 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).

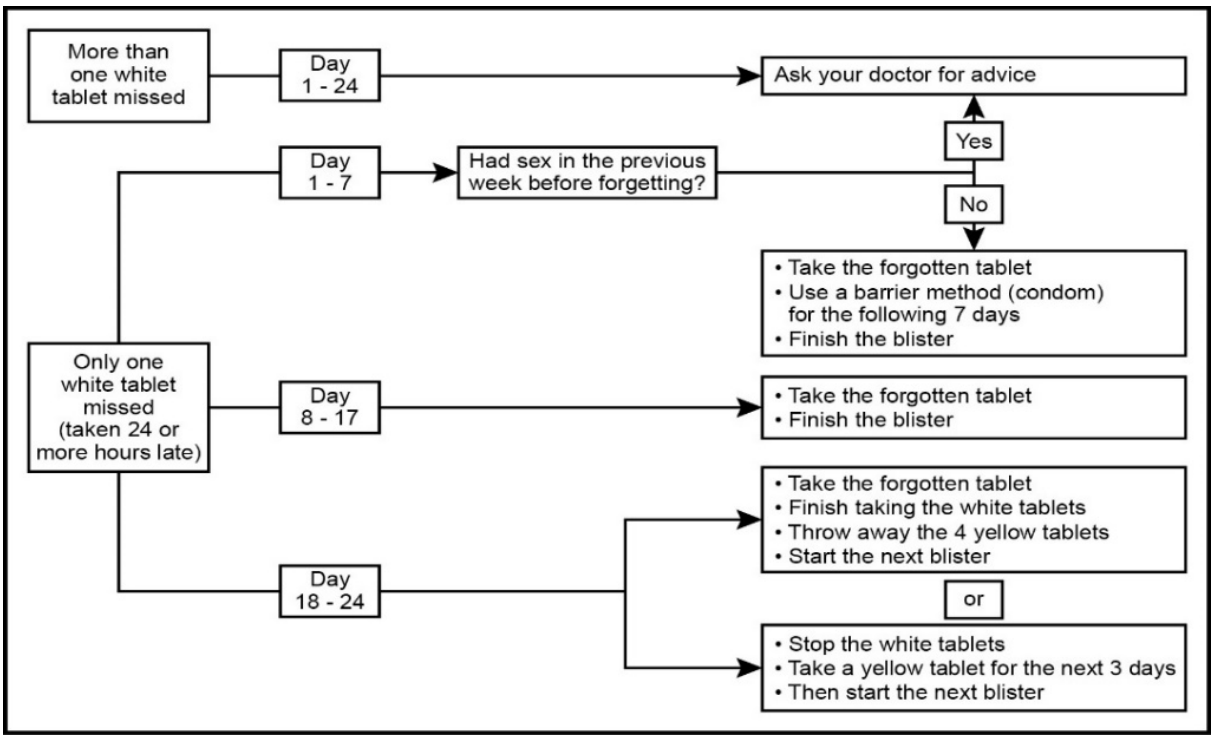
If you have forgotten to take active white tablets in a blister, and you do not have the expected monthly period while taking the yellow placebo tablets from the same blister, you may be pregnant. Consult your doctor before you start with the next blister.

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 for 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 have side effects.

If you get any side effect, particularly if severe or persistent, or have any change to your health that you think may be due to ZOELY, please talk to your doctor.

An increased risk of blood clots in your veins (venous thromboembolism (VTE)) or blood clots in your arteries (arterial thromboembolism (ATE)) is present for all women taking combined hormonal contraceptives. For more detailed information on the different risks from taking combined hormonal contraceptives, please see section 2, 'What you need to know before you take ZOELY'.

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
- rash or itching
- pins and needles

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.
Allergic (hypersensitive) reactions have been reported in users of ZOELY, but the frequency cannot be estimated from the available data.

The following side effects have been linked with the use of ZOELY:
Very common (may affect more than 1 in 10 people):
- acne
- changes to menstrual periods (e.g., absence of menstruation or breakthrough bleeding or spotting)

Common (may affect up to 1 in 10 people):
- decreased interest in sex; depression/depressed mood; mood changes
- headache or migraine
- feeling sick (nausea)
- heavy menstrual periods, breast pain, pelvic pain
- weight gain

Uncommon (may affect up to 1 in 100 people):
- increased appetite, fluid retention (oedema)
- hot flush
- swollen abdomen (belly)
- 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 sex, dryness in the vagina or vulva, spasm of the uterus
- irritability
- increased liver enzymes

Rare (may affect up to 1 in 1,000 people):
- harmful blood clots in a vein or artery, for example:
  - in a leg or foot (i.e., DVT)
  - in a lung (i.e., PE)
  - heart attack
  - stroke
  - mini-stroke or temporary stroke-like symptoms known as a transient ischaemic attack (TIA)
  - blood clots in the liver, stomach/intestine, kidneys or eye.

  The chance of having a blood clot may be higher if you have any other conditions that increase this risk. (See section 2 for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot.)
- decreased 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
- hunger
- disease of the gallbladder

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 3: ‘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 ZOELY, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor, pharmacist or nurse. 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: nomegestrol acetate and estradiol
  - White active film-coated tablets: Each tablet contains nomegestrol acetate 2,5 mg and estradiol (as hemihydrate) 1,5 mg.
  - Yellow placebo film-coated tablets: The tablet does not contain active substances.
- The other ingredients are:
  - Tablet core (white active and yellow placebo film-coated tablets): Lactose monohydrate (see section 2 'ZOELY contains lactose'), microcrystalline cellulose (E460), crospovidone (E1201), talc (E553b), magnesium stearate (E572), silica colloidal anhydrous.
  - Tablet coating (white active film-coated tablets): Polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol, talc (E553b).
  - Tablet coating (yellow placebo tablets): Polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol, talc (E553b), iron oxide yellow (E172) and iron oxide black (E172).

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 (24 white active tablets and 4 yellow placebo tablets).

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