PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed with a doctor's prescription only

ZOELY®
Film-Coated Tablets

Active ingredients:
White active tablets: nomegestrol acetate 2.5 mg / estradiol 1.5 mg (as hemihydrate)
Yellow placebo tablets: The tablets do not contain active ingredients.

Inactive ingredients and allergens in the preparation: See sections 2 "Important information about some of this medicine's ingredients" and 6 "Additional Information".

Important information 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 weeks or more.
- You must be alert and contact your doctor if you think you may have symptoms of a blood clot (see section 2 under "Blood clots").

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

ZOELY is used to prevent pregnancy.

Therapeutic group: sex hormones. Combined pill containing progestogen and oestrogen.

- All 24 white film-coated tablets are active tablets that contain a small amount of two different female hormones. These are nomegestrol acetate (a progestogen) and estradiol (an oestrogen).
- The 4 yellow film-coated tablets are inactive tablets that do not contain hormones and are called placebo tablets.
- Contraceptive pills that contain two different hormones, like **ZOELY**, are called "combined pills".
- Nomegestrol acetate (the progestogen in **ZOELY**) and estradiol (the oestrogen in **ZOELY**) work together to prevent ovulation (release of an egg from the ovary) and to reduce the chance of any released egg being fertilised and making you pregnant.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are sensitive (allergic) to estradiol or nomegestrol acetate, or to any of the additional ingredients contained in the medicine (listed in section 6);

- you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolism, PE) or other organs;
- 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;
- You need surgery, or in situations where you are immobile (you cannot stand on your feet) for a long time (see section "Blood clots");
- you have ever had a heart attack or a stroke;
- you have ever had angina pectoris (a condition that causes severe chest pain and may be a first sign of a blocked blood vessel around the heart, known as a heart attack) or transient ischaemic attack (TIA – temporary stroke symptoms);
- you have any of the following diseases that may increase your risk of a blood clot in the arteries:
  - severe diabetes with blood vessel damage
  - very high blood pressure
  - a very high level of certain fats in the blood (cholesterol or triglycerides)
  - a condition known as hyperhomocysteinaemia (excess homocysteine in the blood);
- you have ever had a type of migraine called "migraine with aura";
- you have ever had inflammation of the pancreas (pancreatitis) associated with high levels of fat in your blood;
- you have ever had severe liver disease and your liver is not yet working normally;
- you have ever had a benign or malignant tumour in the liver;
- you have ever had, or you may have, breast cancer or cancer of the genital organs;
- you have a meningioma or have ever been diagnosed with a meningioma (a generally benign tumour of the tissue layer between the brain and the skull);
- you have any unexplained bleeding from the vagina.

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

General notes
Before you start using **ZOELY**, you should read the information on blood clots (thrombosis) in section 2. It is particularly important to read about the symptoms of a blood clot – see section "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 in order to give you an individual advice on the treatment. 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 the pill, or where the pill protection against pregnancy 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 (safe days method) or temperature methods (taking body temperature method). These methods may not protect against pregnancy because the pill alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.
ZOELY, like other hormonal contraceptives, does not protect against HIV infection (which can cause acquired immunodeficiency syndrome, AIDS) or other sexually transmitted diseases.

Special warnings regarding use of the medicine

Before treatment with **ZOELY**, tell the doctor

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 description of the symptoms of these serious side effects, see section "How to identify a blood clot";
- you notice any changes in your health, especially involving any of the conditions mentioned in this leaflet (see also in section 2 "Do not use the medicine if"; do not forget about the changes in the health of your immediate family);
- you feel a lump in your breast;
- you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing;
- you intend to use other medicines (see also in section 2 "Drug interactions");
- you are going to have limited mobility or are about to undergo surgery (tell your doctor at least four weeks in advance);
- you have unusual, heavy vaginal bleeding;
- you forgot one or more tablets in the first week of the blister pack and had unprotected intercourse in the seven days before (see also in section 3 "If you forget to take the medicine");
- you have severe diarrhoea or severe vomiting;
- you miss a period 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").

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

- Hereditary and acquired angioedema. Consult your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives, together with difficulty breathing. Products containing oestrogens may induce or worsen symptoms of angioedema;
- Epilepsy (see in section 2 "Drug interactions");
- Liver disease (e.g. jaundice) or gallbladder disease (e.g. gallstones);
- Diabetes;
- Depression;
- Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- Systemic lupus erythematosus (SLE – a disease affecting your natural defence system);
- Haemolytic uraemic syndrome (HUS – a disorder of blood clotting causing failure of the kidneys);
- Sickle cell anaemia (an inherited disease of the red blood cells);
- Elevated levels of fat in the blood (hypertriglyceridaemia) or a family history of this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas);
- Inflammation in the veins under the skin (superficial thrombophlebitis);
- Varicose veins;

- 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]);
- You have ever had chloasma (yellowish-brown pigment skin patches, also called "pregnancy patches", particularly on the face). If so, avoid too much exposure to the sun or ultraviolet light;
  In addition, tell the doctor if:
- A close family member has or has had breast cancer
- You need surgery, or in situations where you are immobile (you cannot stand on your feet) for a long time (see section 2 "Blood clots");
- You have just given birth; you are at increased risk for blood clots. You should ask your doctor how long after the birth you can start taking **ZOELY**.

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

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, they may even be fatal.

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

HOW TO IDENTIFY 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 dizziness or light headedness • rapid or irregular heartbeat • severe abdominal pain. 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 that 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 abdomen • 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 • loss of consciousness or fainting with or without seizures. 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.	Stroke
• swelling and slight blue discolouration of the extremities • severe abdominal pain (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 associated 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 deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung, it can cause 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 immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g., below the age of 50). In this case, you may have a hereditary blood clotting disorder;
- if you need surgery, or if you cannot stand on your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of **ZOELY** may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop **ZOELY** ask your doctor when you can start using it again.
- 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 factors you have.
Air travel (>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 the use of **ZOELY** needs to be stopped.
If any of the above conditions change while you are using **ZOELY**, for example a close family member experiences 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 may 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 as a result of 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 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 member of your immediate family has had a heart attack or stroke at a young age (less than about 50). 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 using **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

Breast cancer has been detected slightly more often in women using combined pills, but it is not known whether this is caused by the combined pills. For example, it may be that tumours are found more in women on combined pills because they undergo breast tests by the doctor more often. After stopping the combined pill, the increased risk is gradually reduced.

It is important to check your breasts regularly 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 section 2 “Special warnings regarding use of the medicine”).

In rare cases, benign (noncancerous) liver tumours, and in even more rare cases malignant (cancerous) liver tumours have been reported in pill users. Contact your doctor if you have unusual severe abdominal pain.

Cervical cancer is caused by an infection with the human papilloma virus (HPV). It has been reported to occur more often in women using the pill for more than 5 years. It is unknown if this is due to the use of hormonal contraceptives or to other factors, such as difference in sexual behaviour.

Meningiomas
Use of nomegestrol acetate has been linked to the development of generally benign tumours of the tissue layer between the brain and the skull (meningioma). The risk increases especially when you use high doses for long duration (several years). If you are diagnosed with meningioma, your doctor will stop your treatment with **ZOELY** (see section "Do not use the medicine if"). If you notice any symptoms such as changes in vision (e.g. double or blurred vision), 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.

Tests and follow-up
If you are having any blood or urinary test, 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.

Drug interactions
If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist.
In particular, if you are taking:
- 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, oxcarbazepine, topiramate, felbamate);
  - tuberculosis (e.g., rifampicin);
  - HIV infection (e.g., rifabutin, ritonavir, efavirenz);
  - Hepatitis C virus (HCV) infection (e.g., protease inhibitors);
  - other infectious diseases (e.g., griseofulvin);
  - high blood pressure in the blood vessels in the lungs, known as pulmonary arterial hypertension (bosentan).
- The herbal product Hypericum (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. Since the effect of another medicine on **ZOELY** may last up to 28 days after stopping the medicine, it is necessary to use the barrier contraceptive method for that long.
- Some medicines can increase the levels of the active substances of **ZOELY** in the blood. The effectiveness of the pill is maintained, but tell your doctor if you are using anti-fungal medicines containing ketoconazole.
- **ZOELY** may also interfere with the action of other medicines – such as the anti-epileptic medicine lamotrigine.
- The Hepatitis C virus (HCV) combination drug regimen ombitasvir/paritaprevir/ritonavir with or without dasabuvir, as well as the combination drug 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 drug 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** immediately and contact your doctor.
If you want to stop **ZOELY** because you want to get pregnant, see in section 3 “If you stop taking the medicine”.
ZOELY is not usually recommended for use during breastfeeding. If you wish to use the pill while breastfeeding, check with your doctor.

Driving and using machines
ZOELY has no or negligible effect on your ability to drive and use machines.

Important information about some of this medicine's ingredients
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The recommended dosage is usually:
One tablet each day at about the same time, with some water if necessary. **Do not exceed the recommended dose.**
No information is available with regards to crushing/splitting/chewing the tablets.

When and how to take the tablets
The **ZOELY** blister contains 28 film-coated tablets: 24 white tablets containing the active ingredients (number 1-24) and 4 yellow tablets without active ingredients (number 25-28).
Each time you start a new blister of **ZOELY**, take the number 1 white active 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 Wednesday, use the day label sticker that starts with “WED”. Stick it on the blister, just above the row of white active tablets where it reads “Place day label here”. This allows you to check whether you took your daily tablet.

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

Your period will start during the 4 days of taking the yellow placebo tablets. Usually it will start 2-3 days after the last white active tablet and may not have finished before the next blister is started.
Start taking your next blister immediately after taking the last yellow placebo tablet, even if your period hasn’t 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 roughly the same days each month.

Some women may not have their period every month while using the yellow placebo tablets. If you have taken **ZOELY** every day according to these directions, it is unlikely that you are pregnant (see also section 3 “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). If you start taking **ZOELY** on the first day of your menstrual bleeding, you are protected against pregnancy immediately. You do not need to use additional contraceptive methods.

When changing from another combined hormonal contraceptive (combined pill, vaginal ring or transdermal patch)
You can start taking **ZOELY**, preferably on the day after you have taken the last active tablet (the last pill containing the active ingredient) 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 this is, ask your doctor or pharmacist). You can also start **ZOELY** 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 follow these instructions, it is not necessary to use an additional contraceptive method. If you have any concerns about it, consult your doctor.

When changing from a progestogen-only pill (minipill)
You can switch at any day from the minipill containing progestogen only and start taking **ZOELY** on the next day, but you must also use a barrier method of contraception (e.g., a condom) during the first 7 days of taking **ZOELY**.

When changing from a progestogen-only injectable, implant or a hormone-medicated intrauterine system (IUS)
Start using **ZOELY** when your next injection is due or on the day that your implant or IUS is removed. But if you are having intercourse, make sure you also use a barrier method of contraception for the first 7 days of taking **ZOELY**.

After having a baby
You can start taking **ZOELY** between 21 and 28 days after having a baby. If you start later than day 28, you should also use a barrier method of contraception (e.g., a condom) during the first 7 days of taking **ZOELY**. If, after having a baby, you have had sexual intercourse before starting **ZOELY**, first, be sure that you are not pregnant or wait until the next menstrual period. If you want to start taking **ZOELY** after having a baby and you are breastfeeding, see section 2 “Pregnancy and breastfeeding”.
Ask your doctor or pharmacist what to do if you are not sure when to start.

After a miscarriage or an abortion
Follow the advice of your doctor.

If you have taken a higher dosage
There have been no reports of serious effects due to taking too many **ZOELY** tablets. If you have taken several tablets at a time, you may have nausea, vomiting or vaginal bleeding. If you have taken too many tablets or if you discover that a child has taken **ZOELY**, ask your doctor or pharmacist for advice.

If you forget to take the medicine
The following advice only refers to missed **white active** tablets.

- if you are **less than 24 hours late** in taking the tablet, the pill protection against pregnancy 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 the tablet, the pill protection against pregnancy may be reduced. The more tablets you have forgot, the higher is the risk of getting pregnant. There is a particularly high risk of becoming pregnant if you miss white active tablets at the beginning or at the end of the blister. Therefore, you should follow the rules given below.

Day 1-7 of white active tablet intake (see picture and schedule)
Take the missed white active tablet as soon as you remember even if this means taking two tablets at the same time and continue taking the next tablet 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. In this case, contact your doctor immediately.

Day 8-17 of white active tablet intake (see picture and schedule)
Take the last missed tablet as soon as you remember (even if this means taking two 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 18-24 of white active tablet intake (see picture and schedule)
There is a particularly high risk of becoming pregnant if you miss white active 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.

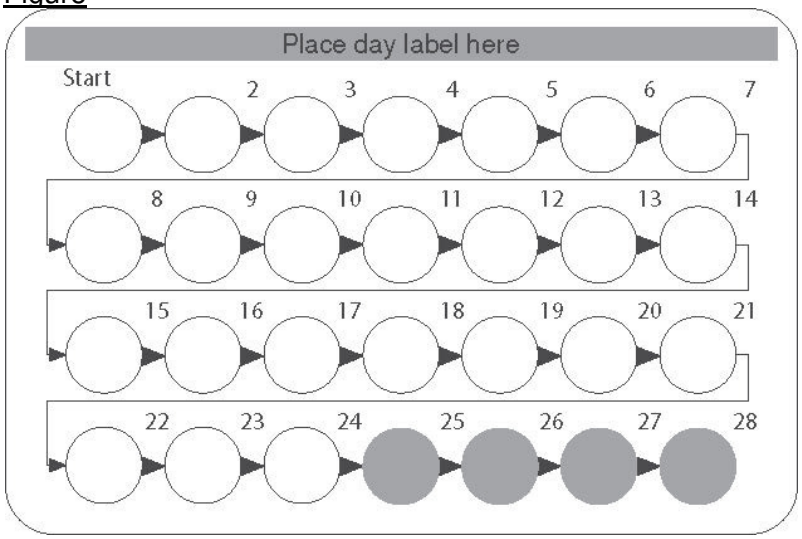
Option 1)
Take the last missed white active tablet as soon as you remember even if this means taking two tablets at the same time and continue taking the next tablets at the usual time. Start the next blister as soon as the white active tablets in the current blister are finished, so you **skip the yellow 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 light or menstruation-like bleeding while taking the white active tablets.

Option 2)
Stop taking the white active tablets and start taking the yellow placebo tablets for a maximum of 3 days so that the total number of yellow placebo tablets plus missed white active tablets is not more than 4. At the end of the yellow placebo tablet intake, start the next blister.

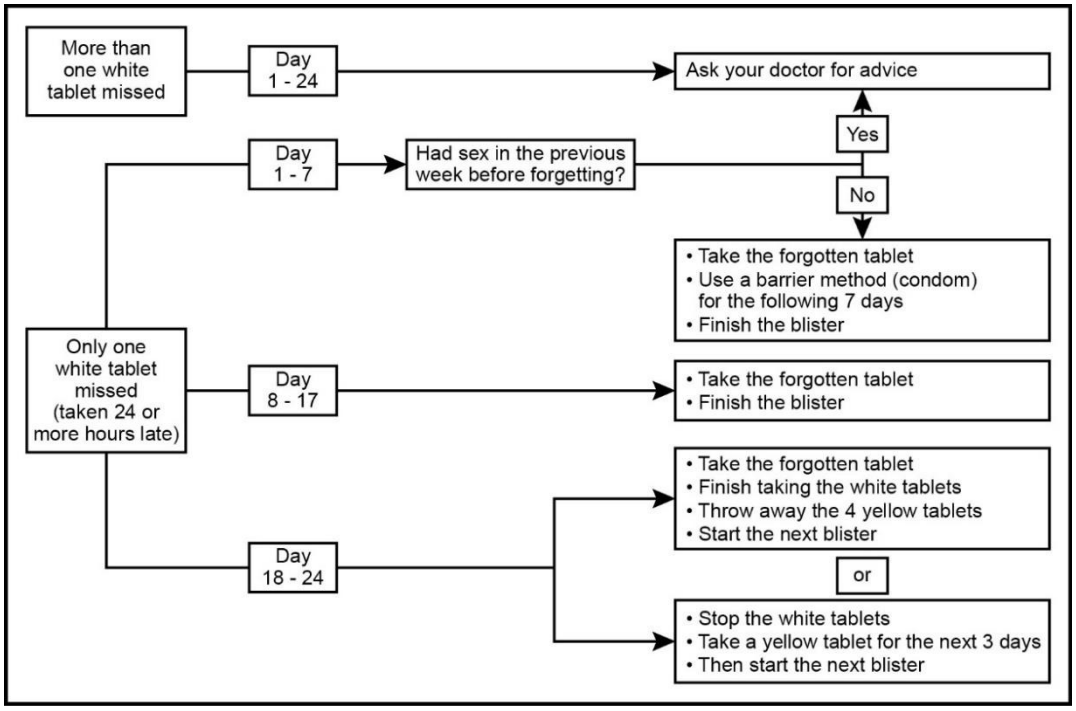
If you cannot remember how many white active tablets you have missed, follow the first option, use a barrier method, such as a condom, as an extra precaution until you have taken your tablets correctly for 7 days in a row, and contact your doctor (as you may not have been protected from being pregnant).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

The following recommendation applies only if you have forgotten to take the **yellow placebo** tablets.
The last 4 yellow tablets of the fourth row are placebo tablets which do not contain active ingredients. If you forgot to take one of these tablets, the protection of **ZOELY** against pregnancy is maintained. Throw away the yellow placebo tablet(s) you missed and start taking the tablets of the next blister at the usual time.

Figure



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



If you vomit or have severe diarrhoea
If you vomit within 3-4 hours of taking a white active tablet, or you have severe diarrhoea, there is a risk that the active ingredients of **ZOELY** tablet have not been completely absorbed into your body. The situation is similar to the situation in which you forgot to take a white active tablet. After vomiting or diarrhoea, you must take another white active tablet from a reserve blister as soon as possible. If possible, take it *within 24 hours* of when you normally 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 the medicine”. If you have severe diarrhoea, please tell your doctor.
The yellow tablets are placebo tablets which do not contain active ingredients. If you vomit or have severe diarrhoea within 3-4 hours of taking a yellow placebo tablet, the pill protection of **ZOELY** against pregnancy is maintained.

If you want to delay your period
Even if it is not recommended, you can delay your period by not taking the yellow placebo tablets from the fourth row and going straight to a new blister of **ZOELY**. You may experience light or menstruation-like bleeding while using the second blister.
When you wish your period to begin during the second blister, stop taking the white active tablets and start taking the yellow placebo tablets. Complete the second blister by taking the 4 yellow placebo tablets, then start taking the next (third) blister. **If you are not sure what to do, consult the doctor or pharmacist.**

If you want to change the starting day of your period
If you take the tablets according to the instructions, then your period will begin during the placebo days. If you have to change this day, reduce the number of placebo days – when you take the yellow placebo tablets – but never increase them (4 is the maximum). For example, if you start taking the yellow placebo tablets on Friday, and you want to change this to a Tuesday (3 days earlier), you must start a new blister 3

days earlier than usual. You may not have any bleeding during the shortened period of yellow placebo tablet intake. While using the next blister, you may have light or menstruation-like bleeding on the days of taking the white active tablets. ***If you are not sure what to do, consult the doctor or pharmacist.***

If you have unexpected bleeding
As with all combined pills, for the first few months, you can have some irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection, but keep taking your tablets as usual. Irregular vaginal bleeding 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 have 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 also in section 3 “If you vomit or have severe diarrhoea” or section 2 under “Drug interactions”.
- If you have **not** taken all the tablets correctly, or if your expected period does not occur 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 stop taking the medicine
You can stop taking **ZOELY** at any time. 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, it is preferable to wait until you have had a natural period before trying to become pregnant. This will help you to determine the future delivery date.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take a medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, ask your doctor or pharmacist.

4. SIDE EFFECTS
As with any medicine, using **ZOELY** may cause side effects in some users.
Do not be alarmed by this list of side effects; you may not experience any of them.

There is an increased risk of blood clots in veins (venous thromboembolism (VTE)) or blood clots in arteries (arterial thromboembolism (ATE)) for all women taking combined hormonal contraceptives. For more detailed information on the different risks due to taking combined hormonal contraceptives, please see section 2 “Before using the medicine”.

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

Very common side effects (affect more than 1 in 10 users):
- acne
- changes in menstrual periods (e.g., absence or irregularity)

Common side effects (affect up to 1 in 10 users):
- decreased interest in sex; depression/depressed mood; mood changes
- headache or migraine
- nausea
- heavy menstrual bleeding; breast pain; pelvic pain
- weight gain

Uncommon side effects (affect up to 1 in 100 users):
- increased appetite; fluid retention (oedema)
- hot flush
- swollen abdomen
- increased sweating; hair loss; itching; dry skin; oily skin
- heaviness in limbs
- regular but scanty periods; breast enlargement; breast lump; milk production while not pregnant; premenstrual symptoms; pain during intercourse; dryness in the vagina or vulva; spasms of the uterus
- irritability
- increased liver enzymes

Rare side effects (affect up to 1 in 1,000 users):
- 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/intestines, 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 the risk of 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

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

Further information on the possible side effect of changes in menstrual periods (e.g., absence or irregularity) 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".

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by entering the link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the blister and carton. The expiry date refers to the last day of that month.
- **Storage conditions:**
  Store below 30°C.
- Combined pills (including **ZOELY** tablets) no longer used should not be disposed via wastewater or the municipal sewage system. The hormonal active ingredients in the tablet may have harmful effects if they reach the aquatic environment. Return them to a pharmacy or dispose of them in another safe way according to local requirements. These measures will help to protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredients, the medicine also contains
Tablet core (white active and yellow placebo film-coated tablets):
Lactose monohydrate, cellulose microcrystalline, crospovidone, talc, magnesium stearate and silica colloidal anhydrous.

Tablet coating (white active film-coated tablets):
Polyvinyl alcohol, titanium dioxide, macrogol 3350/PEG and talc.

Tablet coating (yellow placebo film-coated tablets):
Polyvinyl alcohol, titanium dioxide, macrogol 3350/PEG, talc, iron oxide yellow and iron oxide black.

What the medicine looks like and contents of the pack
The active film-coated tablets are white and round. They are coded 'ne' on both sides.
The placebo film-coated tablets are yellow and round. They are coded 'p' on both sides.
ZOELY pack contains 1 or 3 blisters of 28 film-coated tablets (24 white active film-coated tablets and 4 yellow placebo film-coated tablets) in a carton pack.
Not all pack sizes may be marketed.

Registration holder's name and address Truemed Ltd., 10 Beni Gaon St., Netanya 4250499.

Manufacturer's name and address Theramex Ireland Ltd., Ireland.

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