ZOELY®

Film-Coated Tablets

Active ingredients:

White active tablets: nomegestrol acetate 2.5 mg / estradiol 1.5 mg (as hemihvdrate)

Yellow placebo tablets: The tablet does not contain active ingredients. Inactive and allergenic ingredients in the preparation: See sections 2 "Important information regarding some of the ingredients of the medicine" and 6 "Further Information"

Important things to know about combined hormonal contraceptives

- 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 under "Blood clots").

Read this leaflet carefully in its entirety before using the medicine This leaflet contains concise information about the medicine. If you have any further questions, refer to the 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

1. WHAT IS THE MEDICINE INTENDED FOR?

ZOELY used to prevent pregnancy.

Therapeutic group: sex hormones. Combined pill containing progestogen

- 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 a fertilized egg being leased and becoming pregnant.

2. BEFORE USING THE MEDICINE Do not use the medicine if:

- you are sensitive (allergic) to estradiol or nomegestrol acetate, or to any of the additional ingredients contained in the medicine (listed in 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:
- 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 an operation or if you are off 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 blocked blood vessel in the area of 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 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
- trialvcerides) a condition known as hyperhomocysteinaemia;
- 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
- you have ever had a benign or malignant tumour in the liver; you have ever had, or you may have, cancer of the breast or the genital
- organs: in case of presence or history of meningioma (generally benign tumour
- of the tissue located between the brain and the skull). In case of doubt, contact your doctor:
- 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 tell your doctor. In the meantime, use a non-hormor 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 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 the pill, or where the reliability of the pill 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 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 (AIDS) or any other sexually transmitted disease.

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 a description of the symptoms of these serious side effects please
- go to "How to recognise a blood clot". you notice any changes in your own 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 are going to use other medicines (see also in section 2 "Drug
- you are to be immobilised or are to have surgery (tell your doctor at east 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 experience severe vomiting; you miss 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. If the condition develops, or gets worse while you are using ZOELY, you should also tell your doctor

- 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 (for instance jaundice) or gallbladder disease (for instance gallstones);
- Diabetes: Depression
- Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- Systemic lupus erythematosus (SLE a disease affecting your natural defense 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);

history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the Inflammation in the veins under the skin (superficial thrombophlebitis);

• Elevated levels of fat in the blood (hypertriglyceridaemia) or a family

- 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] (see in section 2 "Special warnings regarding use of the medicine")
- You have ever had chloasma [yellowish-brown pigment skin patches, so 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

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 develor

- in veins (referred to as '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. Rarely, there may be

serious lasting effects or, very rarely, 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 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 loss of consciousness or fainting with or without seizures.	Stroke

BLOOD CLOTS IN A VEIN

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

Sometimes the symptoms of stroke can be brief

you should still seek urgent medical attention as

you may be at risk of another stroke.

vith an almost immediate and full recovery, but

 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

swelling and slight blue discolouration of an | Blood clots

severe pain in your stomach (acute abdomen). | blood vessels

blocking othe

- 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
- 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

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 vear. 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"

Risk of developing a blood clot in a year Women who are **not using** a About 2 out of 10,000 women combined hormonal pill and are

oregnant ·	
men using a combined monal contraceptive pill taining levonorgestrel, ethisterone or norgestimate	
nen 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 ncrease the risk. Your risk is higher:

if you are very overweight (body mass index or BMI over 30 kg/m²); 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 about 50). In this case you could have a hereditary blood clotting disorder;

blister is started.

necessary.

if you need to 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 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

your period on roughly the same days each month.

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 conditions 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 f 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 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 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 advised to stop smoking. If you are unable to stop smoking and are older than 35 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.

Breast cancer has been found 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 gradually reduces.

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.

Cases of meningioma (generally benign tumours of the brain) have been reported with prolonged use (several years) of nomegestrol monotherapy (without estradiol) at higher doses of 3.75 and 5 mg and more (see section Do not use the medicine if"). If a meningioma is diagnosed, treatment

with **ZOELY** should be stopped.

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 if you have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the 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
- 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., boceprevir, telaprevir); 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 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** ess 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 additional barrier contraceptive method for that long. **ZOELY** in the blood. The effectiveness of the pill is maintained, but
- ell your doctor if you are using anti-fungal medicines containing ketoconazole. **ZOELY** may also interfere with the working of other medicines –
- such as the anti-epileptic 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 breast-feeding

Driving and using machines

ZOELY must not be used by women who are pregnant, or who think they nay 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

"If you stop taking the medicine". **ZOELY** is not usually recommended for use during breast-feeding. If you rish to use the pill while breast-feeding, check with your doctor.

Important information about some of the ingredients of the medicine 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 the medicine as instructed by the doctor. You should check with your doctor or pharmacist if you are not sure regarding the dosage

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

and how to use the medicine. Dosage and way of treatment will be determined by the doctor only.

The recommended dosage is generally: 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

When and how to take the tablets

The **ZOELY** blister contains 28 film-coated tablets: 24 white tablets with the active substances (number 1-24) and 4 vellow tablets without active substances (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 a 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

Follow the direction of the arrows on the blister, so use the white active 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 2-3 days after the last white active tablet and may not have finished before the next

Start taking your next blister immediately after 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

Some women may not have their period every month while using the vellow 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 an additional contraceptive method.

When changing from another combined hormonal contraceptive

(combined pill, vaginal ring or transdermal patch) You can start taking ZOELY, preferable 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).

n 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, refer to your doctor.

When changing from a progestogen-only pill (minipill)

You can switch every day from the minipill containing progestogen only and start taking ZOELY the next day, but you must also use a barrier me 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 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, you should also use a barrier method of contraception (e.g., a condom) during the first 7 days of **ZOELY** use. 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 menstrua period. If you want to start ZOELY after having a baby and are breasteeding, see also section 2 "Pregnancy and Breast-feeding"

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 took a higher dosage There have been no reports of serious effects from taking too many **ZOELY** tablets. If you have taken several tablets at a time, you may have nausea vomiting or vaginal bleeding. If you took 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 a 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 any 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 white active missed tablet as soon as you remember even f 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

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

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. Take the last missed white active tablet as soon as you remember even f 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 **skip the yellow placebo tablets**. You may not have your period until you take the yellow lacebo tablets at the end of the second blister, but you may have mild r breakthrough bleeding while taking the white active tablets.

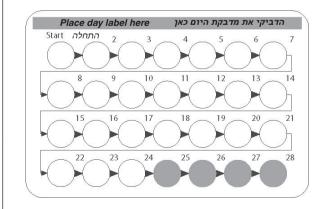
have taken your tablets correctly in the 7 days prior to the missed tablet.

Option 2) Stop taking the white active tablets and start taking the vellow placebo tablets for a maximum of 3 days so that the total number of placebo plus missed white active tablets is not more than 4. At the end of the yellow placebo tablet interval, start the next bliste f you cannot remember how many white active tablets you have missed,

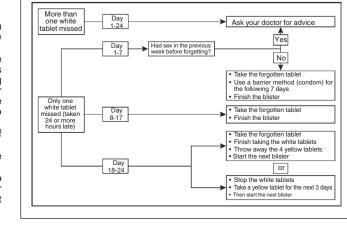
follow the first option, use a barrier method such as a condom as an extra precaution until you have taken your tablets correctly for 7 days n a row, and contact your doctor (as you may not have been protected from being pregnant). If you have forgotten to take white active tablets in a blister, and you do not have the expected monthly period while taking the vellow placebo

tablets from the same blister, you may be pregnant. Refer to the doctor before vou start with the next blister The following recommendations apply only if you have forgotten to take the **vellow placebo** tablets.

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 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. Picture



Schedule: if you are 24 or more hours late 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 **ZOÉLY** tablet not have been completely absorbed into your body. The situation is similar to if you forget 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 **ZOELY**". If you have severe diarrhoea, please tell your doctor.

The yellow tablets are placebo tablets which do not contain active substances. If you vomit or have severe diarrhoea within 3-4 hours of taking a yellow placebo tablet, the pill protection of ZOELY against pregnancy

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 this second blister. When you wish your period to begin during the second blister, stop taking the white active tablets and start taking the vellow placebo tablets. Complete the second blister by taking the 4 vello 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 vellow placebo tablet intake. While using the next blister you may have mild or breakthrough bleeding on white active tablet-taking days.

If you are not sure what to do, consult the doctor or pharmacist. If you have unexpected bleeding 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.

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 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 stop taking the medicine

If you have missed one or more periods

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 when the baby will be due.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them. If you have any further questions on the use of this medicine, ask

4. SIDE EFFECTS As with any medicine, use of **ZOELY** can cause side effects, in some of

Do not be alarmed by reading the list of side effects, you may not suffer

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 letailed information on the different risks from taking combined hormonal contraceptives, please see section 2 "Before using the medicine"

decreased interest in sex; depression/depressed mood; mood changes

The following side effects have been linked with the use of **ZOELY**: Very common side effects (affects more than 1 in 10 users):

- changes to menstrual periods (e.g., absence or irregularity) Common side effects (affects up to 1 in 10 users):
- headache or migraine heavy menstrual periods; breast pain; pelvic pain
- weight gair **Uncommon side effects** (affects up to 1 in 100 users):

from any of them.

- 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 syndrome; pain during intercourse; dryness in the vagina or vulva; spasm of the uterus
- increased liver enzymes
- Rare side effects (affects 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 \circ mini-stroke or temporary stroke-like symptoms known as a transient
- 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
- the conditions that increase risk for blood clots and the symptoms of a blood clot).

hunger

ischaemic attack (TIA)

- decreased appetite increased interest in sex
- disturbance in attention dry eye; contact lens intolerance drv mouth • golden brown pigment patches, mostly in the face; excessive hair growth

vaginal smell; discomfort in the vagina or vulva

bleeding' and 'If you have missed one or more periods

online side effects reporting form, or by using the link:

disease of the gallbladder Allergic (hypersensitive) 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 changes to menstrual periods (e.g., absence or irregular) during the use of **ZOELY** is described

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult w the doctor. Side effects can be reported to the Ministry of Health by using the link Reporting side effects due to medicinal treatment" at the home page of

the Ministry of Health's web site (www.health.gov.il) which refers to the

n section 3 'When and how to take the tablets', 'If you have unexpected

conditions that increase this risk (See section 2 for more information on

https://sideeffects.health.gov.il 5. HOW TO STORE THE MEDICINE?

Store below 30°C.

- Avoid Poisoning! This medicine, as all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. 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 Storage conditions:

Combined pills (including **ZOELY** tablets) no longer required 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 them in another safe way according to local requirements These measures will help to protect the environment.

Polyvinyl alcohol, titanium dioxide, macrogol 3350/PEG, talc, iron oxide yellow and iron oxide black. on both sides.

6. FURTHER INFORMATION

What the medicine looks like and contents of the pack The active film-coated tablets are white and round. They are coded 'ne'

In addition to the active ingredients, the medicine also contains:

magnesium stearate and silica colloidal anhydrous.

Tablet coating (yellow placebo film-coated tablets)

Tablet coating (white active film-coated tablets):

Tablet core (white active and yellow placebo film-coated tablets):

Polyvinyl alcohol, titanium dioxide, macrogol 3350/PEG and talc.

Lactose monohydrate, cellulose microcrystalline, crospovidone, talc,

The placebo film-coated tablets are yellow and round. They are coded n both sides. **ZOELY** comes in 1 or 3 blisters of 28 film-coated tablets (24 white active

film-coated tablets and 4 yellow placebo film-coated tablets) packed in Not all pack sizes may be marketed.

License Holder and Address Truemed Ltd., 10 Beni Gaon St., Netanya 4250499.

Manufacturer and Address Theramex Ireland limited, Dublin, Ireland Revised on December 2021 according to MOH guidelines.

Drug registration no. listed in the official drugs registry of the Ministry

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