

ZOELY[®] FILM-COATED TABLETS

Nomegestrol Acetate/Estradiol (2.5mg/1.5mg)

What is in this leaflet

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What *ZOELY* is used for

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

- All 24 white tablets are active tablets that contain a small amount of two different female hormones. These are nomegestrol acetate (a progestagen) and estradiol (the natural estrogen).
- The 4 yellow tablets do not contain hormones and are called placebo tablets.
- Contraceptive pills that contain two hormones, like *ZOELY*, are called ‘combined pills’.
- If you were previously using the pill, please note that *ZOELY* contains estradiol, the estrogen which is identical to the natural hormone produced by your ovaries, as opposed to

the commonly used synthetic estrogen ethinylestradiol.

- Nomegestrol acetate, the progestogen in *ZOELY*, is derived from the hormone progesterone. Progesterone is produced by your ovaries.

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

How *ZOELY* works

ZOELY releases two female sex hormones that prevent the release of an egg cell from the ovaries. If no egg is released you cannot become pregnant. In addition, *ZOELY* causes changes in the cervical mucus which also helps to prevent pregnancy.

Before you take *ZOELY*

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.

- When you must not take it

In some situations **you should not use** a combined pill.

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

- if you are allergic to estradiol or nomegestrol acetate, or any of the other ingredients of *ZOELY*.
- if you have (or have ever had) a blood clot in a blood vessel (venous thrombosis) of your legs, lungs (pulmonary embolus) or other organs. For possible signs of a blood clot see in section ‘**Blood clots (Thrombosis)**’.

- if you have ever had a heart attack or a stroke.
- if you have (or have ever had) a condition that may be a first sign of a heart attack (such as angina pectoris which causes severe chest pain) or stroke (such as transient ischaemic attack [a TIA – a slight temporary stroke]).
- if you have a disease that may increase the risk of a clot in the arteries. This applies to the following diseases:
 - diabetes with damaged blood vessels
 - very high blood pressure
 - a very high level of fat in the blood (cholesterol or triglycerides).
- if you have a disorder affecting your blood clotting – for instance, protein C deficiency.
- If you have major surgery (e.g., an operation) and your ability to move around is limited for a long period of time (see section ‘**Blood clots (Thrombosis)**’).
- if you have (had) a type of migraine called ‘migraine with aura’.
- if you have (had) inflammation of the pancreas (pancreatitis) associated with high levels of fat in your blood.
- if you have (had) severe liver disease and your liver is not yet working normally.
- if you have (had) a benign or malignant tumour in the liver.
- if you have (had), or if you may have, cancer of the breast or the genital organs.
- if you are pregnant or think you might be pregnant.

If any of these conditions appear for the first time while using *ZOELY*, stop taking it at once and tell your doctor. In the meantime, use a non-hormonal contraceptive. See also ‘Things to be careful of.’
- Before you start to take it

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In some situations **you need to take special care** while using a combined pill.

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

- if you have hereditary 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 estrogens may induce or worsen symptoms.
- if a close relative has or has ever had breast cancer.
- if you have epilepsy (see in *'Taking other medicines'*).
- if you have liver disease (for instance jaundice) or gallbladder disease (for instance gallstones).
- if you have diabetes.
- if you have depression.
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease).
- if you have SLE (systemic lupus erythematosus; a disease affecting your natural defense system).
- if you have HUS (haemolytic uremic syndrome; a disorder of blood clotting causing failure of the kidneys).
- if you have sickle cell disease (an inherited disease of the red blood cells).
- if you have elevated fatty acid levels in the blood (hypertriglyceridaemia) or a positive family history for this condition (familial hypertriglyceridaemia). If so, you may be at an increased risk of developing pancreatitis (inflammation of the pancreas) when using combined pills.
- if you have a condition that occurred for the first time or

worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, porphyria [a disease of the blood], herpes gestationis [skin rash with vesicles during pregnancy], Sydenham's chorea [a disease of the nerves in which sudden movements of the body occur] (see section **'When should you contact your doctor?'**)).

- if you have (or have ever had) chloasma [yellowish-brown pigment patches, so called 'pregnancy patches', particularly on the face]. If so, avoid too much exposure to the sun or ultraviolet light.
- if you have recently given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start using *ZOELY* (see section **'Blood clots (Thrombosis)'**).
- if you need an operation, or if your ability to move around is limited for a long period of time (see section **'Blood clots (Thrombosis)'**).

Blood clots (Thrombosis)

Blood clots in a vein

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

Using a combined pill containing ethinylestradiol increases a woman's risk of developing such clots compared with a woman not taking any combined pill. The risk of developing a blood clot in a vein is highest during the first year a woman uses the pill. The risk is also higher if you restart using a combined pill (the same product or a different product) after a break of 4 weeks or more.

The risk is not as high as the risk of developing a blood clot during pregnancy. *ZOELY* contains estradiol instead of ethinylestradiol. It is not yet known how *ZOELY* influences the risk of getting a

blood clot compared with other contraceptive pills.

The risk of blood clots in a vein increases:

- with increasing age;
- if one of your close relatives has had a blood clot in the leg, lung or other organ at a young age;
- if you are overweight; if you must have an operation, or if your ability to move around is limited for a long period of 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 section *'When you must not take it'*.
- If you gave birth less than a few weeks ago.

Blood clots in an artery

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

The risk of a blood clot in an artery increases:

- with increasing age;
- **if you smoke. When using a combined hormonal contraceptive like *ZOELY* you are strongly advised to stop smoking, especially if you are older than 35 years;**
- if you are overweight;
- if you have high blood pressure;
- if a close relative has had a heart attack or stroke at a young age;

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- if you have a high level of fat in your blood (cholesterol or triglycerides);
- if you get migraines;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm).

Symptoms of blood clots

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

- an unusual sudden cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe, or long-lasting headache or worsening of migraine;
- partial or complete loss of vision, or double vision;
- slurring or speech disability;
- sudden changes to your hearing, sense of smell, or taste;
- dizziness or fainting;
- weakness or numbness in any part of your body;
- severe pain in your abdomen;
- severe pain or swelling in either of your legs.

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

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

Cancer

The information given below was obtained from studies with combined pills containing ethinylestradiol, but may also apply to *ZOELY*.

Breast cancer has been found slightly more often in women using combined pills, but it is not known whether this is caused by the treatment itself. For example, it

may be that tumours are found more in women on combined pills because they are examined by the doctor more often. The increased occurrence of breast cancer becomes gradually less after stopping the combined pill.

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 section 'Before you start to take it').

In rare cases, benign (noncancerous) 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 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 a long time. It is unknown if this finding is due to the use of hormonal contraceptives or to sexual behaviour and other factors (such as better cervical screening).

For users of the high-dose combined ethinylestradiol pills it has been reported that cancer of the endometrium (the lining of the womb) and cancer of the ovaries occur less frequently. This may also be the case for low-dose ethinylestradiol containing pills and pills containing the natural estradiol, but this has not been confirmed.

- Taking other medicines

Always tell the doctor who prescribes *ZOELY* which medicines or herbal products you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the dispensing pharmacist) that you use *ZOELY*. 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);
 - tuberculosis (e.g. rifampicin);
 - HIV infections (e.g. ritonavir, nevirapine, nelfinavir, efavirenz);
 - fungal infections (e.g. griseofulvin);
 - 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.
- Some medicines can increase the levels of the active substances of *ZOELY* in the blood. The reliability of the pill is maintained, but tell 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.

Important information about some of the ingredients of *ZOELY*
ZOELY contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before starting with *ZOELY*.

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More about combined pills

The combined pill may also have non-contraceptive health benefits.

- Your period may be lighter and shorter. This particularly applies to a product like *ZOELY* which is presented in a 24/4 regimen.
- During the use of *ZOELY* the concentration of folic acid in your blood remains unchanged.
- *ZOELY* has no negative effect on the level of fat in your blood (cholesterol and triglyceride).
- *ZOELY* has no negative effect on your sugar and insulin blood levels.
- *ZOELY* has no negative effect on certain parameters in your blood that relate to blood clot formation.
- *ZOELY* decreases the concentrations of certain androgenic hormones in your blood.

How to take ZOELY- How much to take, When to take it, How long to take it

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

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

Take each day one tablet at about the same time, with some water if necessary. 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 2-3 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 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 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 also section '**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 2-5 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 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 progestagen-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 progestagen-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 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

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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 breast-feeding, see also section '**Breast-feeding**'.

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 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 **12 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 1-7 of 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 two tablets at the same time) and take 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. So contact your doctor immediately.

Day 8-17 of active white 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 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 active white 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. 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 white 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 2 active white tablets, you should take 2 days of the placebo yellow tablets; and 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.

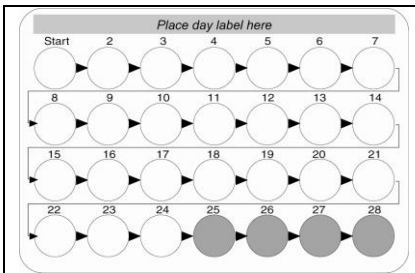
Yellow placebo tablets missed

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.

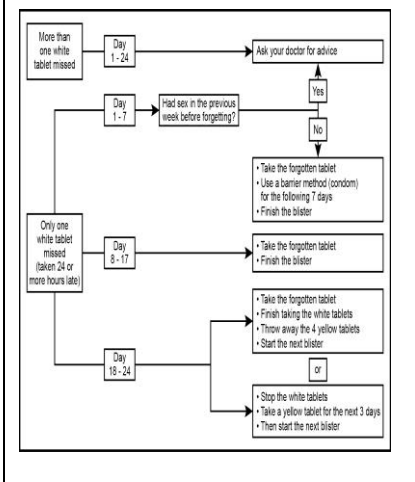
Picture

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



- If you take too much (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.

While you are using ZOELY

If you vomit or have severe diarrhea

If you vomit within 3-4 hours of taking an active white tablet, or you have severe diarrhea, 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 diarrhea, you must take

another active white 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 diarrhea, please tell your doctor.

The yellow tablets are placebo tablets which do not contain active substances. If you vomit or have severe diarrhea within 3-4 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 for as long as you wish, until this blister is empty. When you wish your period to begin, just stop tablet-taking. While using the second blister you may have some spotting (drops or flecks of blood) or breakthrough bleeding on 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 your 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

With all combined pills, 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 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 diarrhea, or used other medicines, then it is very unlikely that you are pregnant. Keep taking ZOELY as usual. See also in section '**If you vomit or have severe diarrhea**' or in section '**Taking other medicines**'.
- 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

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have had a natural period before trying to conceive. This helps you to determine when the baby will be due.

When should you contact your doctor?

Regular check-ups

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

Contact your doctor as soon as possible if:

- if you notice any changes in your own health, especially involving any of the items mentioned in this leaflet (see also section 'When you must not take it' and 'Before you start to take it'); do not forget about 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 section 'Taking other medicines');
- if your ability to move around is limited for a long period of time or you are to have surgery (tell your doctor at least 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 intercourse in the seven days before (see also section 'If you forget to take ZOELY');
- if you have severe diarrhea;
- if you miss your periods and suspect you may be pregnant (do not start the next blister pack until your doctor tells you, see also section 'If you have missed one or more periods').

Stop taking tablets and contact your doctor immediately if you

notice possible signs of a blood clot. The symptoms are described in section 'Blood clots (Thrombosis)'.

- Things you must do

General notes

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.

- Things you must not do

Use in adolescents

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

Pregnancy

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

If you want to stop ZOELY because you want to get pregnant, see in section '**If you want to stop taking ZOELY**'.

Breast-feeding

ZOELY is not usually recommended for use during breast-feeding. If you wish to use the pill while breast-feeding, please seek the advice of your doctor.

- Things to be careful of

Laboratory tests

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.

Driving and using machines

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

Side effects

Like all medicines, ZOELY can cause side effects, although not everybody gets them. Contact your doctor if you notice any unwanted effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by the pill.

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

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

- acne
- changes in the menstrual cycle (e.g. absence of menstruation or breakthrough bleeding/spotting)

Common (affects 1 to 10 users in 100):

- 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 (affects 1 to 10 users in 1,000):

- increased appetite; fluid retention (oedema)
- hot flush
- swollen abdomen

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- 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; pain during intercourse; dryness in the vagina or vulva; spasm of the uterus
- irritability
- increased liver enzymes

Rare (affects 1 to 10 users in 10,000):

- 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

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

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 '**How to take ZOELY**', '**If you have unexpected bleeding**' and '**If you have missed one or more periods**'.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by

calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI)

Storage and disposal of ZOELY

- Storage

Keep out of the reach and sight of children.
Store below 30°C.

- Disposal

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.

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

Product description

- What it looks like

ZOELY comes in 1 or 3 blisters of 28 film-coated tablets (24 active white tablets and 4 yellow placebo tablets) packed in a ply carton. Not all pack sizes may be marketed. 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.

- Ingredients

- Active ingredients

The active ingredients are:
in the active white tablets:
nomegestrol acetate (2.5 mg) and estradiol (as hemihydrate) (1.5 mg)
in the yellow placebo tablets: no active substances

- Inactive ingredients

The inactive ingredients are:

Tablet core (active white and yellow placebo tablets):

Lactose monohydrate, Cellulose microcrystalline, Crospovidone, Talc, Magnesium stearate and Silica colloidal anhydrous

Tablet coating (active white tablets):

Poly(vinyl alcohol), Titanium dioxide, Macrogol and Talc

Tablet coating (yellow placebo tablets):

Poly(vinyl alcohol), Titanium dioxide, Macrogol, Talc, Iron oxide yellow and Iron oxide black

- MAL number:

MAL13035063AZ

Product Manufacturer

ORGANON (IRELAND) LTD
P.O. BOX 2857, DRYNAM ROAD, SWORDS, CO DUBLIN, IRELAND.

Product Registration Holder

Merck Sharp & Dohme (Malaysia) Sdn. Bhd.
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