

Package leaflet: Information for the user

Zoely® 2.5 mg/1.5 mg film-coated tablets

Nomegestrol acetate/estradiol

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Important things to know about combined hormonal contraceptives (CHCs):

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

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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1. What Zoely is and what it is used for

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

- All 24 white film-coated tablets are active tablets that contain a small amount of two different female hormones. These are noregestrol acetate (a progestogen) and estradiol (an oestrogen).
- The 4 yellow 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’.
- Estradiol, the oestrogen in Zoely, is identical to the hormone produced by your ovaries during a menstrual cycle.
- Noregestrol acetate, the progestogen in Zoely, is derived from the hormone progesterone. Progesterone is produced by your ovaries during a menstrual cycle.

2. What you need to know before you use Zoely

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.

When you should not use Zoely

You should not use Zoely if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor. Your doctor will discuss with you what other form of birth control would be more appropriate.

- if you 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;
- if you know you have a disorder affecting your blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin – III deficiency, Factor V Leiden or antiphospholipid antibodies;
- if you need an operation or if you are off your feet for a long time (see section ‘Blood clots’);
- if you have ever had a heart attack or a stroke;
- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA – temporary stroke symptoms);
- if you have 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 fat in the blood (cholesterol or triglycerides);
 - a condition known as hyperhomocysteinaemia
- if you have (or have ever had) a type of migraine called ‘migraine with aura’;

- if you have (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 have any unexplained bleeding from the vagina.
- if you are allergic to estradiol or norgestrel acetate, or any of the other ingredients of this medicine (listed in section 6).

If any of these conditions appear for the first time while using Zoely, stop taking it at once and tell your doctor. In the meantime, use a non-hormonal contraceptive. See also ‘General Notes’ in section 2 above.

When to take special care with Zoely

When should you contact your doctor?

Seek urgent medical attention

- if you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e., deep vein thrombosis), a blood clot in the lung (i.e., pulmonary embolism), a heart attack or a stroke (see “Blood clots” section below).

For a description of the symptoms of these serious side effects please go to “How to recognise a blood clot.”

- if you notice any changes in your own health, especially involving any of the items mentioned in this leaflet (see also in section 2 ‘When you should not use Zoely’; do not forget about the changes in the health of your immediate family);
- if you feel a lump in your breast;
- if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing;
- if you are going to use other medicines (see also in section 2 ‘Other medicines and Zoely’);
- if you are to be immobilised or are to have surgery (tell your doctor at least four weeks in advance);
- if you have unusual, heavy vaginal bleeding;
- if you forgot two tablets or more in the first week of the blister pack and had intercourse in the seven days before (see also in section 3 ‘If you forget to take Zoely’);
- if you have severe diarrhoea;
- if you miss periods and suspect you may be pregnant (do not start the next blister pack until your doctor tells you, see also in section 3 ‘If you have missed one or more periods’).

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.

- 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 oestrogens may induce or worsen symptoms of angioedema;
- if a close relative has or has ever had breast cancer;
- if you have epilepsy (see in section 2 ‘Other medicines and Zoely’);
- if you have liver disease (for instance jaundice) or gallbladder disease (for instance gallstones);
- if you have diabetes;
- if you have depression;
- if you have Crohn’s disease or ulcerative colitis (chronic inflammatory bowel disease);
- if you have systemic lupus erythematosus (SLE - a disease affecting your natural defense system);
- if you have haemolytic uraemic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys);

- if you have sickle cell anaemia (an inherited disease of the red blood cells);
- if you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas);
- if you need an operation or if you are off your feet for a long time (see in section 2 ‘Blood clots’).
- if you have just given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking Zoely.
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- if you have varicose veins.
- 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 in section 2 ‘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;

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 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?
<ul style="list-style-type: none"> • swelling of one leg or along a vein in the leg or foot especially when accompanied by: <ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • sudden unexplained breathlessness or rapid breathing; • sudden cough without an obvious cause, which may bring up blood; • sharp chest pain which may increase with deep breathing; • severe light headedness or dizziness; • rapid or irregular heartbeat; • severe pain in your stomach; <p>If you are unsure, talk to a doctor as some of these symptoms such as</p>	Pulmonary embolism

coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g., a 'common cold').	
Symptoms most commonly occur in one eye: <ul style="list-style-type: none"> • immediate loss of vision or • painless blurring of vision which can progress to loss of vision 	Retinal vein thrombosis (blood clot in the eye)
<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • 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 seizure. <p>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.</p>	Stroke
<ul style="list-style-type: none"> • swelling and slight blue discolouration of an extremity; • severe pain in your stomach (acute abdomen). 	Blood clots blocking other blood vessels

BLOOD CLOTS IN A VEIN

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

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

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

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

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

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

What is the risk of developing a blood clot?

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

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

- Out of 10,000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains levonorgestrel, norethisterone, or norgestimate, about 5-7 will develop a blood clot in a year.
- It is not yet known how 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	Not yet known

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 30kg/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;
- 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 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 if you are unsure. Your doctor may decide that Zoely needs to be stopped.

If any of the above conditions change while you are using Zoely, for example a close family member 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.

Cancer

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 are examined 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 “When to take special care with Zoely”).

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 other factors, such as difference in sexual behaviour.

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.

Children and adolescents

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

Other medicines and Zoely

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription and herbal medicines.

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.

- 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, oxcarbazepine, topiramate, felbamate);
 - tuberculosis (e.g. rifampicin);
 - HIV infections (e.g. ritonavir, nevirapine, nelfinavir, efavirenz);
 - other infectious diseases (e.g. griseofulvin);

- high blood pressure in the blood vessels in the lungs (bosentan).
- The herbal product St. John's wort may also stop Zoely from working properly. If you want to use herbal products containing St. John's wort while you are already using Zoely you should consult your doctor first.
- 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 working of other medicines – such as the anti-epileptic lamotrigine.

Pregnancy and breast-feeding

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 3 'If you stop taking Zoely'.

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.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

Zoely contains lactose

Zoely contains lactose. 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 to use Zoely

When and how to take the tablets

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 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 necessary.

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 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 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). Zoely will work 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 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 follow these instructions, it is not necessary to use an additional contraceptive method.

When changing from a progestogen-only pill (minipill)

You can stop taking the minipill any day and start taking Zoely the next day. 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.

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 during the first 7 days of Zoely use. If, after having a baby, you have had sexual intercourse 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 2 'Pregnancy and Breast-feeding'.

Ask your doctor 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 take more Zoely than you should

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.

If you forget to take Zoely

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

- if you are **less than 12 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 **more than 12 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 **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 last white active 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 as an extra precaution for the next 7 days.

If you had sexual intercourse in the week before missing the tablets, there is a possibility of becoming pregnant. So 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. The protection against pregnancy is not reduced, and you do not need to take extra precautions. However, if you have missed more than 1 tablet, you should use extra precautions for 7 days.

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.

Two options can be followed:

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 take 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 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 white active tablet immediately and go directly to the yellow placebo tablet interval. At the end of the placebo tablet interval, start with the next blister.

If you cannot remember how many white active tablets you have missed, follow the first option, use a barrier method as a precaution for the next 7 days and contact your doctor.

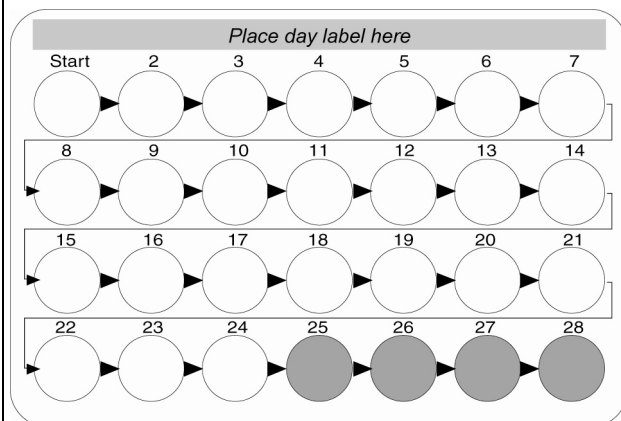
If you have forgotten to take white active tablets in a blister, and you do not have the expected monthly period while taking the yellow placebo tablets from the same blister, you may be pregnant.

Consult your doctor before you start with the next blister.

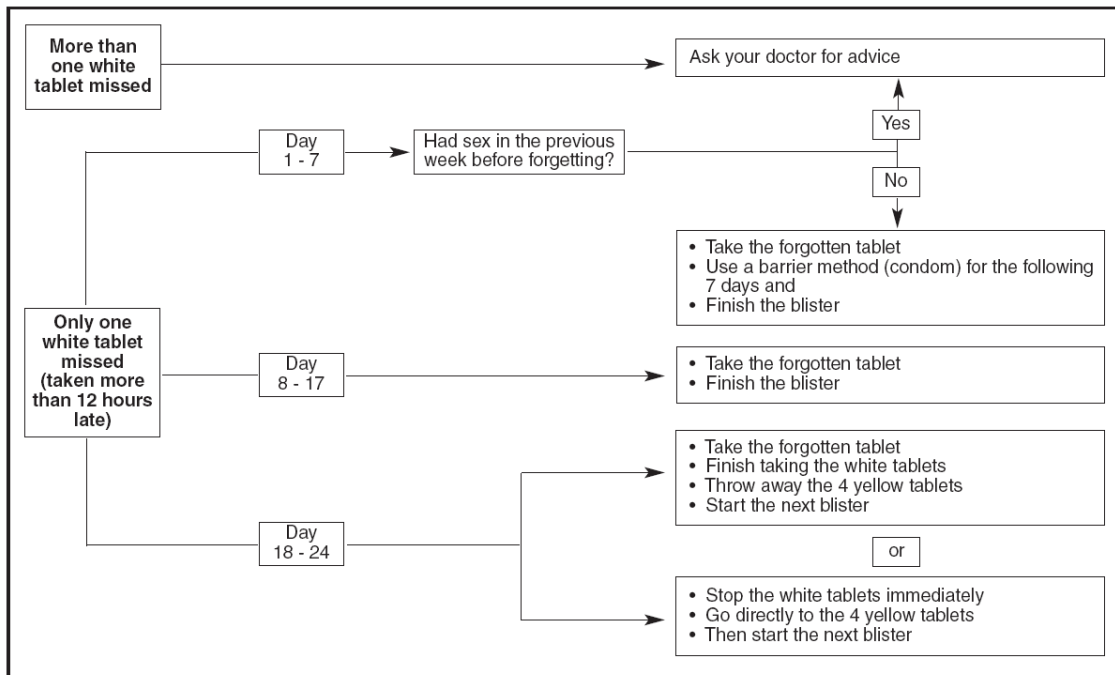
Yellow placebo tablets missed

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

Picture



Schedule: if you are more than 12 hours late taking white 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, the active ingredients of your Zoely tablet may 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 12 hours* of when you normally take your pill. If this is not possible or 12 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 tablet, the reliability of Zoely is maintained.

If you want to delay your period

You can delay your period by not taking the yellow placebo tablets 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 yellow placebo tablets. After finishing the 4 yellow placebo tablets from the second blister, start with the next (third) blister.

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 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 some spotting (drops or flecks of blood) or breakthrough bleeding on white active tablet-taking days.

If you are not sure what to do, consult your doctor.

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.

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 in section 2 'Other medicines and Zoely'.
- If you have **not** taken all the tablets correctly, or if your expected period does not happen twice in a row, you may be pregnant. Contact your doctor immediately. Do not start the next blister of Zoely until your doctor has checked that you are not pregnant.

If you stop taking Zoely

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, you are recommended to wait until you have had a natural period before trying to conceive. This will help you to determine when the baby will be due.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, Zoely can cause side effects, although not everybody gets them.

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

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

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

Very common (may affect more than 1 in 10 people):

- acne
- changes to menstrual periods (e.g. absence or irregularity)

Common (may affect up to 1 in 10 people):

- decreased interest in sex; depression/depressed mood; mood changes
- headache or migraine
- feeling sick (nausea)
- heavy menstrual periods; breast pain; pelvic pain
- weight gain

Uncommon (may affect up to 1 in 100 people):

- increased appetite; fluid retention (oedema)
- hot flush
- swollen abdomen
- 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 (may affect up to 1 in 1,000 people):

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

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

- decreased appetite
- increased interest in sex
- disturbance in attention
- dry eye; contact lens intolerance
- dry mouth
- golden brown pigment patches, mostly in the face; excessive hair growth
- vaginal smell; discomfort in the vagina or vulva
- hunger
- disease of the gallbladder

Allergic (hypersensitive) reactions have been reported in users of Zoely, but the 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 in section 3 'When and how to take the tablets', 'If you have unexpected bleeding' and 'If you have missed one or more periods'.

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

United Kingdom: Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard

Ireland: IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.imb.ie, e-mail: imbpharmacovigilance@imb.ie

Malta: ADR Reporting, The Medicines Authority, Post-Licensing Directorate, 203 Level 3, Rue D'Argens, GŻR-1368 Gżira Website: www.medicinesauthority.gov.mt e-mail: postlicensing.medicinesauthority@gov.mt

5. How to store Zoely

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special 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.

6. Contents of the pack and other information

What Zoely contains

- The active substances are:
in the white active film-coated tablets: Each tablet contains 2.5 mg nomegestrol acetate and 1.5 mg estradiol (as hemihydrate).
in the yellow placebo film-coated tablets: The tablet does not contain active substances.
- The other ingredients are:
Tablet core (white active and yellow placebo film-coated tablets):
Lactose monohydrate (see section 2 'Zoely contains lactose'), cellulose microcrystalline (E460), crospovidone (E1201), talc (E553b), magnesium stearate (E572) and silica colloidal anhydrous
Tablet coating (white active film-coated tablets):
Poly(vinyl alcohol) (E1203), titanium dioxide (E171), macrogol 3350 and talc (E553b)
Tablet coating (yellow placebo film-coated tablets):
Poly(vinyl alcohol) (E1203), titanium dioxide (E171), macrogol 3350, talc (E553b), iron oxide yellow (E172) and iron oxide black (E172)

What Zoely looks like and contents of the pack

The active film-coated tablets (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 comes in 1, 3, 6 or 13 blisters of 28 film-coated tablets (24 white active film-coated tablets and 4 yellow placebo film-coated tablets) packed in a ply carton.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Theramex S.r.l.
Via Messina 38
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Italy

Manufacturer

Organon (Ireland) Limited
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.

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