ZOELY®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ZOELY?

ZOELY contains the active ingredient nomegestrol acetate and estradiol. ZOELY is an oral contraceptive, used to prevent pregnancy.

For more information, see Section 1. Why am I using ZOELY? in the full CMI.

2. What should I know before I use ZOELY?

Do not use if you have ever had an allergic reaction to nomegestrol acetate, estradiol or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use ZOELY? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZOELY and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use ZOELY?

- ZOELY needs to be taken every day at the same time, to ensure it works effectively. Follow all instructions given to you by your doctor.

More instructions can be found in Section 4. How do I use ZOELY? in the full CMI.

5. What should I know while using ZOELY?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using ZOELY. • Monitor your health and contact your doctor if you notice any changes.

	• Keep all of your doctor's appointments and go for regular checkups.
Things you should not do	• Do not stop using this medicine suddenly without telling your doctor. • Do not use this medicine if you are pregnant, or fall pregnant while taking this medicine.
Driving or using machines	• ZOELY is not expected to affect your ability to drive or operate machinery. If you experience any side effects which impact your ability to drive or operate machinery when taking this medicine, act appropriately and contact your doctor.
Drinking alcohol	• Alcohol is not expected to interact with ZOELY. If you drink alcohol, talk to your doctor about the possible effects of taking alcohol with this medicine.

Looking after your medicine	• Store ZOELY in a cool dry place, out of direct light, where the temperature is below 30°C. • Keep ZOELY in the original packaging, in a safe place, away from children.

For more information, see Section 5. What should I know while using ZOELY? in the full CMI.

6. Are there any side effects?

The most common side effects are changes in menstrual cycle, acne, mood changes and headaches. Serious side effects include blood clots in the veins or blood vessels and breast cancer. See more information under ‘The Pill and Thrombosis’ and ‘The Pill and Cancer’.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

ZOELY®

Active ingredient(s): *Nomegestrol Acetate and Estradiol*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZOELY. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZOELY.**

Where to find information in this leaflet:

1. Why am I using ZOELY?
2. What should I know before I use ZOELY?
3. What if I am taking other medicines?
4. How do I use ZOELY?
5. What should I know while using ZOELY?
6. Are there any side effects?
7. Product details

1. Why am I using ZOELY?

ZOELY contains the active ingredient nomegestrol acetate and estradiol. ZOELY is an oral contraceptive, commonly known as a "Birth Control Pill" or "The Pill" that has been prescribed to prevent you from getting pregnant.

ZOELY prevents pregnancy in several ways:

- **It inhibits the egg release by stopping it maturing.**
- **It changes the cervical mucus consistency making it more difficult for sperm to reach the egg.**
- **It changes the lining of the uterus making it less suitable for implantation.**

Oral contraceptives are an effective method of birth control. When taken correctly (without missing tablets) the chance of becoming pregnant is very low.

The following non-contraceptive health benefits have been associated with the combined Pill:

- Your periods may be lighter and shorter. As a result, the risk of anaemia may be lower.
- Your period pains may become less severe or may completely disappear.

2. What should I know before I use ZOELY?

Warnings

Do not use ZOELY if:

- you are allergic to nomegesterol acetate or estradiol, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or troubled breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

If you have any of the following conditions, tell your doctor before starting ZOELY. Your doctor may advise you to use a different type of Pill or an entirely different (non-hormonal) method of birth control.

- a blood clot (venous thrombosis) in a blood vessel of your legs, lungs (embolus) or other organs
- a heart attack or stroke
- 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 a transient ischaemic attack)
- a serious risk factor or several risk factors for developing a blood clot
- very high blood pressure
- a very high level of fat in the blood (cholesterol or triglycerides)
- a condition called hyperhomocysteinaemia
- 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 have major surgery (e.g., an operation) and your ability to move around is limited for a long period of time
- diabetes mellitus with blood vessel damage
- a history of migraine accompanied by e.g. visual symptoms, speech disability, or weakness or numbness in any part of the body
- pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood
- jaundice (yellowing of the skin) or severe liver disease and your liver is not yet working normally
- a benign or malignant liver tumour
- a cancer that may grow under the influence of sex hormones (e.g. of the breast or of the genital organs)
- meningioma or have ever been diagnosed with a meningioma (a generally benign tumour of the tissue layer between the brain and the skull)
- any unexplained vaginal bleeding
- you are pregnant or think you might be pregnant.

If any of these conditions appear for the first time while using the Pill, stop taking it at once and tell your doctor. In the meantime, use non-hormonal contraceptive measures.

Do not take ZOELY if the expiry date printed on the pack has passed.

Do not take ZOELY if the packaging is torn or shows signs of tampering.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Tell your doctor immediately if you are pregnant or think you are pregnant while you are using ZOELY.

ZOELY must not be used during pregnancy.

ZOELY is not recommended for use during breastfeeding. If you wish to take the Pill while breastfeeding, please seek the advice of your doctor.

Before using ZOELY:

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 sex 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.

If you are concerned about contracting a sexually transmitted infection (STI), ask your partner to wear a condom when having sexual intercourse with you.

ZOELY will not protect you from HIV (AIDS) or any other sexually transmitted infections. To help protect yourself from STIs, you need to use a barrier contraceptive such as a condom, but even barrier contraceptives may not protect you against human papilloma virus (HPV).

You should have a thorough medical check-up, including a Pap smear, breast check, blood pressure check and urine check.

You must tell your doctor if you are allergic to any foods, dyes, preservatives or any other medicines.

You must tell your doctor if you smoke.

The risk of having a heart attack or stroke increases as you get older. It also increases the more you smoke. When using the Pill you should stop smoking, especially if you are older than about 35 years of age.

You must tell your doctor if you have any of the conditions listed below. You may need to be kept under close observation. Your doctor can explain this to you. Tell your doctor if:

- anyone in your immediate family has had breast cancer
- you have hereditary and acquired angioedema
- you suffer from epilepsy
- you are overweight
- you have diabetes
- you have depression
- you have high blood pressure

- you have a heart valve disorder or a certain heart rhythm disorder
- anyone in your immediate family has had a thrombosis, a heart attack, or a stroke
- you have sickle cell disease you have liver disease (jaundice) or gall bladder disease
- you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- you have systemic lupus erythematosus (SLE, a disease affecting the skin all over the body)
- you have haemolytic uraemic syndrome (HUS; a disorder of blood coagulation causing failure of the kidneys)
- 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
- an inflammation in the veins under the skin (superficial thrombophlebitis)
- varicose veins
- you have a condition that occurred for the first time or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, a metabolic disease called porphyria, a skin disease called herpes gestationis, a neurological disease called Sydenham's chorea)
- you have or have had chloasma (yellow brownish pigmentation patches on the skin, particularly of the

face); if so, avoid too much exposure to the sun or ultraviolet radiation

- 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
- You need an operation or if your ability to move around is limited for a long period of time. This includes travelling by plane for greater than 4 hours.

Tell your doctor if any of the above conditions appear for the first time, recur, or worsen while using the Pill.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Medicines that may <u>reduce</u> the effect of ZOELY include:

- medicines for epilepsy such as
  - phenytoin,
  - primidone,
  - barbiturates such as phenobarbital,
  - carbamazepine,
  - oxycarbamazepine,
  - topiramate,
  - felbamate

- medicines for tuberculosis (e.g. rifampicin and rifabutin)
- medicines for HIV infections (ritonavir, nevirapine, nelfinavir, efavirenz)
- medicines for Hepatitis C virus infection (e.g. boceprevir, telaprevir)
- antibiotics (e.g. penicillin, ampicillin, tetracyclines)
- antifungals (e.g. griseofulvin)
- medicines for high blood pressure in the blood vessels of the lungs (bosentan)
- herbal medicines containing St John's Wort primarily for the treatment of depressive moods

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.

If you are taking medicines or herbal products that might make ZOELY less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on ZOELY may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive method for that long.

ZOELY may also interfere with the working of other medicines - such as ciclosporin and the anti-epileptic lamotrigine.

The Hepatitis C virus (HCV) combination drug regimens ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin; glecaprevir/

pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZOELY.

4. How do I use ZOELY?

How much to take

- follow the instructions provided and use ZOELY until your doctor tells you to stop.

When to use ZOELY

- **Take your medicine at the same time each day.**

Taking ZOELY at the same time each day will have the best effect. It will also help you remember when to take it.

How to take ZOELY

A ZOELY pack contains strips of 28 tablets: 24 white tablets with active substances and 4 yellow tablets that do not contain active substances. Each time you start a new strip of ZOELY, take the first white active tablet in the left-hand top corner (see 'Start').

Choose from the 7 stickers with day indicators the one that begins with your starting day, e.g. if you start on a Wednesday, use the day label sticker that starts 'WED'. Stick it on the strip, 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 liquid if necessary.

Follow the direction of the arrows on the pack taking the white active tablets first followed by the yellow inactive tablets.

A period should begin during the 4 days that you use the yellow inactive tablets (the withdrawal bleed). Usually it will start on day 2-3 after the last white tablet and may not have finished before the next strip is started.

Start taking your next pack immediately after the last yellow inactive tablet, even if your period hasn't finished. This means you will always start new packs on the same day of the week, and also means that you have your period on about the same days, each month.

When no hormonal contraception has been used in the past month

Start taking ZOELY on the first day of your cycle, i.e. the first day of menstrual bleeding. ZOELY will work immediately, it is not necessary to use an additional contraceptive method.

You may also start on days 2-5 of your cycle, but in that case 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 (COC), no problem vaginal ring, or transdermal patch)

You can start taking ZOELY the day after you take the last tablet from your present Pill pack. If your present Pill pack contains inactive tablets (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 the present Pill (or the day after the last inactive tablet of your present Pill).

In case you use a vaginal ring or transdermal patch, you should start using ZOELY preferably on the day of removal, but at latest when the next ring or patch would have been applied.

If you have used the Pill, patch or ring consistently and correctly and if you are sure that you are not pregnant, you can stop taking the Pill or remove the ring or patch on any day and start using ZOELY immediately.

If you follow these instructions, it is not necessary to use an additional contraceptive method.

When changing from a progestogen-only method (minipill)

You can stop taking the minipill any day and start taking ZOELY the next day, at the same time. But make sure you also use an additional contraceptive method (a barrier method) for the first 7 days of tablet-taking.

When changing from an injectable, an implant or a progestogen-releasing intrauterine device (IUD)

Start using ZOELY when your next injection is due or on the day that your implant or your IUD is removed. Make sure you also use an additional contraceptive method (a barrier method) for the first 7 days of tablet-taking.

After having a baby

If you have just had a baby, your doctor may tell you to wait until after your first normal period before you start taking ZOELY. Sometimes it is possible to start sooner. Your doctor will advise you. If you are breast-feeding and want to take ZOELY, you should discuss this first with your doctor.

After a miscarriage or abortion

Your doctor will advise you.

Additional contraceptive precautions

When additional contraceptive precautions are required you should either abstain from vaginal sex, or use a barrier method of contraception, a condom, or a cap (diaphragm) plus spermicide. Rhythm methods are not advised as the Pill disrupts the cyclical changes associated with the natural menstrual cycle e.g., changes in temperature and cervical mucus.

If you forget to take ZOELY

The following advice only refers to missed white active tablets

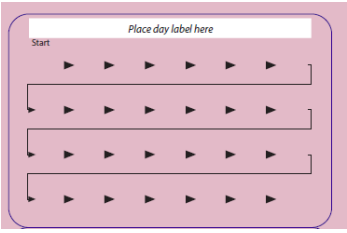
If you are less than 24 hours late in taking a tablet,

- the reliability of the Pill is maintained. Take the tablet as soon as you remember and take further tablets at the usual time.

If you are 24 or more hours late in taking any tablet,

- the reliability of the Pill may be reduced. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased. There is a particularly high risk of becoming pregnant if you miss white active tablets at the beginning or at the end of the strip. Therefore, you should follow the rules given below.

Picture 1



Day 1-7 (the first 7 days of white active tablet intake, see picture 1 and the schedule at the end of this leaflet)

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 tablets at the usual time. 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 pregnant. So tell your doctor immediately.

Days 8 to 17 from the first white active tablet intake (see picture 1 and the schedule at the end of this leaflet)

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 (the last 7 days of white active tablet intake, see picture 1 and the schedule at the end of this leaflet)

There is a particularly high risk of becoming pregnant if you miss white active tablets close to the yellow placebo tablet interval. By adjusting your intake schedule this higher risk can be prevented.

The following two options can be followed. You do not need to use extra precautions if you have taken your tablets correctly in the 7 days prior to the missed tablet. If this is not the case, you should follow the first of these two options and use a barrier method such as a condom as an extra precaution until you have taken your tablets correctly for 7 days in a row.

Option 1

Take the last missed white active tablet as soon as you remember (even if this means taking 2 tablets at the same time) and take the next tablets at the usual time. Start the next strip as soon as the white active tablets in the current strip 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 strip, 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. At the end of this interval, start the next blister.

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.

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

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

Yellow 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 tablet that you missed and continue taking the next tablets at the usual time.

You want to delay your period

You can delay your period if you continue with the white active tablets in your next pack of ZOELY immediately after finishing the white tablets in your current pack. You can continue with this pack for as long as you wish, until this pack is empty. When you wish your period to begin,

just stop tablet-taking. While using the second pack you may have some breakthrough bleeding or spotting on active tablet-taking days. Start your next pack after the usual 4-day inactive tablet interval.

You want to change the starting day of your period

If you take your tablets as directed, you will have your period on about the same day every 4 weeks. If you want to change this, just shorten (never lengthen) the next placebo tablet interval. For example, if your period usually starts on a Friday and in future you want it to start on Tuesday (3 days earlier) you should now start your next pack 3 days sooner than you usually do. If you make your placebo tablet interval very short (e.g. 3 days or less), you may not have a bleeding during the interval. You may have some breakthrough bleeding or spotting during the use of the white tablets in the next pack.

If you vomit or have diarrhoea

If you vomit within 3-4 hours of taking an active white tablet, or you have severe diarrhoea, the active ingredients of your ZOELY tablet may not have been completely absorbed into your body. The situation is similar to if you forget an active white tablet. After vomiting or diarrhoea, you must take 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 "What to do if… you forget to take your tablets". If you have severe diarrhoea, please contact your doctor.

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

If you have unexpected bleeding

With all Pills, for the first few months, you can have breakthrough bleeding or spotting between your periods. You may need to use sanitary protection but continue to take your tablets as normal. Breakthrough bleeding or spotting usually stops once your body clock has adjusted to the Pill (usually after about 3 tablet-taking cycles). Tell your doctor if it continues, becomes heavy or starts again.

If you have missed a period

If you have taken all of your tablets at the right time, and you have not vomited, or had severe diarrhoea or used other medicines then you are very unlikely to be pregnant. Continue to take ZOELY as usual.

If you miss your period twice in a row, you may be pregnant. Do not start the next pack of ZOELY until your doctor has checked you are not pregnant.

If you use too much ZOELY

There have been no reports of serious harmful effects from taking too many ZOELY tablets at one time. If you take too much ZOELY you may feel sick, vomit, or have vaginal bleeding.

If you discover a child has taken ZOELY, ask your doctor for advice.

If you are not sure of what to do:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor or go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ZOELY?

Things you should do

When you are using the Pill, your doctor will tell you to return for regular check-ups. You should have a check-up at least once a year.

Call your doctor straight away if you:

- notice any changes in your own health, especially involving any of the items mentioned in this leaflet; do not forget about the items related to your immediate family
- feel a lump in your breast
- experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing
- are going to use other medicines

- notice your ability to move around is limited for a long period of time or you are to have surgery (consult your doctor at least 4 weeks in advance)
- have unusual, heavy vaginal bleeding
- forgot tablets at the beginning or end of the pack and had intercourse in the seven days before
- have severe diarrhoea
- miss your period twice in a row or suspect you are pregnant. Do not start the next pack until told to by your doctor.

Remind any doctor, dentist, or pharmacist you visit that you are using ZOELY.

Stop taking tablets and see your doctor immediately if you notice possible signs of thrombosis, myocardial infarction, or a stroke such as:

- an unusual cough
- severe pain in the chest which may reach the left arm - this discomfort may include the back, jaw, throat, arm, stomach
- feeling of being full, having indigestion or choking
- sweating, nausea, vomiting, anxiety
- breathlessness or rapid breathing
- any unusual, sudden, severe, or prolonged headache or migraine attack
- partial or complete loss of vision, or double vision
- confusion, slurring or speech disability
- sudden changes to your hearing, sense of smell or taste
- dizziness or fainting

- fast or irregular heartbeat
- weakness or numbness in any part of your body
- severe pain in your stomach
- severe pain or swelling in either of your legs
- pain or tenderness in the leg which may be felt only when standing or walking
- warmth, red or discoloured skin on the leg
- sudden pain, swelling and slight blue discoloration of an extremity
- sudden trouble walking, loss of balance or coordination

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ZOELY affects you.

ZOELY is not expected to affect your ability to drive or operate machinery. If you experience any side effects which impact your ability to drive or operate machinery when taking this medicine, act appropriately and contact your doctor.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol is not expected to interact with ZOELY. If you drink alcohol, talk to your doctor about the possible effects of taking alcohol with this medicine.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Keep your tablets in the original pack until it is time to take them. If you take your tablets out of the pack, they may not keep well.

Store ZOELY in a cool dry place below 30°C, away from moisture, heat, or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Changes to mood and feelings: • mood changes • depression/depressed mood • irritability • changes to appetite • decreased or increased interest in sex • disturbance in attention **Changes to skin, hair, and tissues:** • acne • hair loss • oily skin • dry skin • dry mouth • dry eyes • itching • excessive hair growth • increased sweating • larger breasts	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• golden brown pigment patches, mostly in the face **Changes to menstrual cycle:** • breakthrough bleeding or spotting • absence of menstruation • regular but scanty periods • premenstrual syndrome **Changes to reproductive system:** • pelvic pain • swollen abdomen • milk production while not pregnant • pain during intercourse • dryness in the vagina or vulva • spasms of the uterus • vaginal smell • discomfort in the vagina or vulva **Other:** • headache or migraine • feeling sick (nausea)	

Less serious side effects	What to do
• weight gain • fluid retention • sensation of heaviness • hot flushes • increase in the levels of liver enzymes	

Serious side effects

Serious side effects	What to do
Relating to Cancer: • breast pain • lumps in breast **Relating to Thrombosis:** • headache or pain elsewhere in the body • dizziness • fainting • disturbances in vision • swollen ankles • yellowing of the eyes or skin	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

The Pill and Thrombosis

A thrombosis is the formation of a blood clot which may block a blood vessel.

A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this blood clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called "pulmonary embolism". Deep venous thrombosis is a rare occurrence. It can develop whether or not you are taking the Pill. The risk is higher in Pill-users than in non-users. The chance of getting a thrombosis 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. Thrombosis can also happen if you become pregnant. The risk of thrombosis also increases if you gave birth less than a few weeks ago. ZOELY contains estradiol instead of ethinylestradiol. ZOELY may have a risk of VTE in the same range as observed with a combined hormonal contraceptive that contains levonorgestrel/ethinyl estradiol.

Blood clots can also occur very rarely in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke). Extremely rarely blood clots can occur in the liver, gut, kidney or eye.

Very occasionally thrombosis may cause serious permanent disabilities or may even be fatal.

If you develop high blood pressure while using the Pill, you may be told to stop using it.

The risk of having deep venous thrombosis is temporarily increased as a result of an operation or immobilisation (for example when you have your leg or legs in plaster or splints). In women who use the Pill, the risk may be yet higher. Tell your doctor you are using the Pill well in advance of any expected hospitalisation or surgery. Your doctor may tell you to stop taking the Pill several weeks before surgery or at the time of immobilisation. Your doctor will also tell you when you can start taking the Pill again after you are back on your feet.

If you notice possible signs of a thrombosis, stop taking the Pill and consult your doctor immediately.

The Pill and Cancer

Regularly examine your breasts.

The information given below was obtained from studies of women who used combined oral hormonal contraceptives, as the combined pill containing ethinylestradiol, and from an additional study that included both oral and non-oral hormonal contraceptive-users.

In studies with the combined Pill, breast cancer has been diagnosed slightly more often in women who use the Pill than in women of the same age who do not use the Pill. This slight increase in the numbers of breast

cancer diagnoses gradually disappears during the course of the 10 years after stopping use of the Pill.

In the additional study that included both oral and non-oral hormonal contraceptive-users, the occurrence of breast cancer was reported to increase the longer the women used the contraceptive. The difference in the reported risk of breast cancer between women who have never used the contraceptive and those who had used the contraceptive was small: 13 additional cases of breast cancer per 100,000 women-years.

It is not known whether this is caused by the Pill. It may be that the women were examined more often, so that the breast cancer was noticed earlier.

Tell your doctor immediately if you have severe pain in your stomach.

In rare cases benign liver tumours and even more rarely, malignant liver tumours have been reported in users of the Pill. These tumours may lead to internal bleeding.

Chronic infection with Human Papilloma Virus (HPV) is the single most important risk factor for cervical cancer. HPV is a sexually transmitted infection. In women who use combined oral contraceptives for a long time the chance of getting cervical cancer may be slightly higher. This finding may not be caused by the Pill itself but may be related to sexual behaviour and other factors.

Meningiomas

Use of nomegestrol acetate (an ingredient in ZOELY), has been linked to the development of a generally benign tumour of the tissue layer between the brain and

the skull (meningioma). The risk increases especially when you use it at high doses and for longer duration (several years). If you are diagnosed with meningioma, your doctor will stop your treatment with ZOELY. If you notice any symptoms such as changes in vision (e.g. seeing double or blurriness), hearing loss or ringing in the ears, loss of smell, headaches that worsen with time, memory loss, seizures, weakness in your arms or legs, you must tell your doctor straight away.

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ZOELY contains

Active ingredient **(main ingredient)**	**In the white tablets:** • nomegestrol acetate 2.5 milligrams • estradiol 1.5 milligrams **In the yellow tablets:** No active ingredients
Other ingredients **(inactive ingredients)**	**In the white tablets:** • lactose monohydrate • microcrystalline cellulose • crospovidone • purified talc • magnesium stearate • colloidal anhydrous silica • polyvinyl alcohol • titanium dioxide • macrogol 3350 **In the yellow tablets:**

	• lactose monohydrate • microcrystalline cellulose • crospovidone • purified talc • magnesium stearate • colloidal anhydrous silica • poly vinyl alcohol • titanium dioxide • iron oxide yellow • iron oxide black • macrogol 3350

Do not take this medicine if you are allergic to any of these ingredients.

What ZOELY looks like

ZOELY is presented in 1 or 3 PVC/Aluminium backed blister strips containing 28 film-coated tablets (24 white active tablets and 4 yellow inactive tablets).

The blister is packed in a carton together with the package leaflet. Each carton also contains a single paper sleeve, designed to carry one strip of tablets when removed from the outer carton.

The white, round active tablets are coded with 'ne' on both sides. The yellow, round inactive tablets are coded with 'p' on both sides.

Australia Registration Number:

ZOELY oral-contraceptive AUST R 168332

Who distributes ZOELY

Theramex Australia Pty Ltd

Level 22, 60 Margaret Street,

Sydney NSW 2000

1800 THERAMEX or 1800 843 726

This leaflet was updated in August 2025.