

General Information		Technical Check		Non Printing Colours	
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Dimensions:	390 x 650	Resent Date:	-	2.	
Manf. Site:	Delpharm Lille	Approval Date:	-	3.	
Min pt size:	9pt	Colours / Plates	1. Black  2. PMS 5205 	3.	5.
SKU:				4.	6.
Proof Round:	3				
Origination Date:	01-12-25				
Originated by:	BW				
Revision Date:	09-12-25				
Revised by:	BW				

- 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 antiepileptic lamotrigine.
- The Hepatitis C virus (HCV) combinations regimens ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin; glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see section 4.4) 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 regimen. Your doctor will advise you.

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 immediately and contact your doctor.
If you want to stop Zoely because you want to get pregnant, see in section 3 'If you stop taking Zoely'.

Zoely is not usually recommended for use during breastfeeding. If you wish to use the pill while breast-feeding, you should check with your doctor.

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

Driving and using machines

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

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

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

When and how to take the tablets

The Zoely blister contains 28 film-coated tablets: 24 white tablets with the active substances (number 1-24) and 4 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'. Place 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 you use the last white active tablet and may not have finished before you start the next blister.

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

Some women may not have their period every month when they are using the yellow placebo tablets. If you have taken Zoely every day according to these directions, it is unlikely that you are pregnant (see also section 3 'If you have missed one or more periods').

Starting your first pack of Zoely

If you have not used a contraceptive with hormones in the previous month

Begin with Zoely on the first day of the cycle (that is the first day of your period). If you start Zoely on the first day of your period you are immediately protected against pregnancy. You do not need to use an additional contraceptive method.

Changing from another combined hormonal contraceptive (combined pill, vaginal ring, or transdermal patch)
You can start Zoely preferably on the day after you have taken the last active tablet (the last tablet containing the active substances) of your present pill blister (this means no tablet-free break). If your present pill blister also contains inactive (placebo) tablets you can start Zoely on the day after taking the last **active** tablet (if you are not sure which this is, ask your doctor or pharmacist). You can also start Zoely later, but never later than the day following the tablet free break of your present pill (or the day after the last inactive tablet of your present pill). In case you change from a vaginal ring or transdermal patch, it is best to start Zoely on the day you remove the ring or patch. You can also start, at the latest, on the day you would have started using the next ring or patch.
If you follow these instructions, it is not necessary to use an additional contraceptive method. If you have any concerns about whether you are protected please seek the advice of your doctor.

Changing from a progestogen-only pill (minipill)

You can switch any day from the progestogen-only pill to start Zoely on the next day, but you must use a barrier method of contraception (for example, a condom) during 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 must use a barrier method of contraception (for example, a condom) during the first 7 days that you are taking Zoely. If, after having a baby, you have had sex before starting Zoely, you must first be sure that you are not pregnant or you must wait until your next period.

If you are breast-feeding and want to start Zoely after having a baby, see section 2 'Pregnancy and Breast-feeding'. Ask your doctor or pharmacist what to do if you are not sure when to start.

After a miscarriage or an abortion

Follow the advice of your doctor.

If you take more Zoely than you should

There have been no reports of serious harm from taking too many Zoely tablets. If you have taken several tablets at once, then, you may feel sick (nausea), vomit or bleed from the vagina. If you have taken too many Zoely tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

If you forget to take Zoely

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

- if you are **less than 24 hours late** taking a tablet, the pill protection against pregnancy is maintained. Take the tablet as soon as possible and then take the next tablets at the usual time.
- if you are **24 or more hours late** taking a tablet, the pill protection against pregnancy may be reduced. The more tablets you have forgotten, the higher your risk of becoming pregnant. There is a particularly high risk of becoming pregnant if you miss **white** active tablets at the beginning or at the end of the blister. Therefore you should follow the rules given below.

Day 1-7 of white active tablet intake (see picture and schedule)

Take the forgotten white active tablet as soon as possible even if this means that you have to take two tablets at the same time and continue to take the next tablet at the usual time. However, use a barrier method of contraception (for example a condom) as an extra precaution until you have taken your tablets correctly for 7 days in a row. If you had sex in the week before missing the tablets, there is a possibility of you becoming or being pregnant. In that case, contact your doctor immediately.

Day 8-17 of white active tablet intake (see picture and schedule)

Take the last missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time. If you have taken your tablets correctly in the 7 days prior to the missed tablet, the protection against pregnancy is not reduced, and you do not need to use extra precautions. However, if you have missed more than 1 tablet, use a barrier method such as a condom as an extra precaution until you have taken your tablets correctly for 7 days in a row.

Day 18-24 of white active tablet intake (see picture and schedule)

There is a particularly high risk of you 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 of contraception (for example 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 possible even if this means that you have to take two tablets at the same time and continue to 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 light or menstruation like bleeding while taking the white active tablets.

Option 2

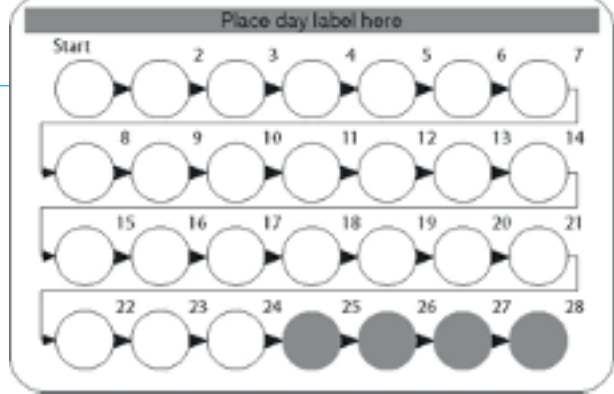
Stop taking the white active tablets and start taking the yellow placebo tablets for a maximum of 3 days so that the total number of placebo plus missed white active tablets is not more than 4. At the end of the yellow placebo tablets intake, start the next blister.

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

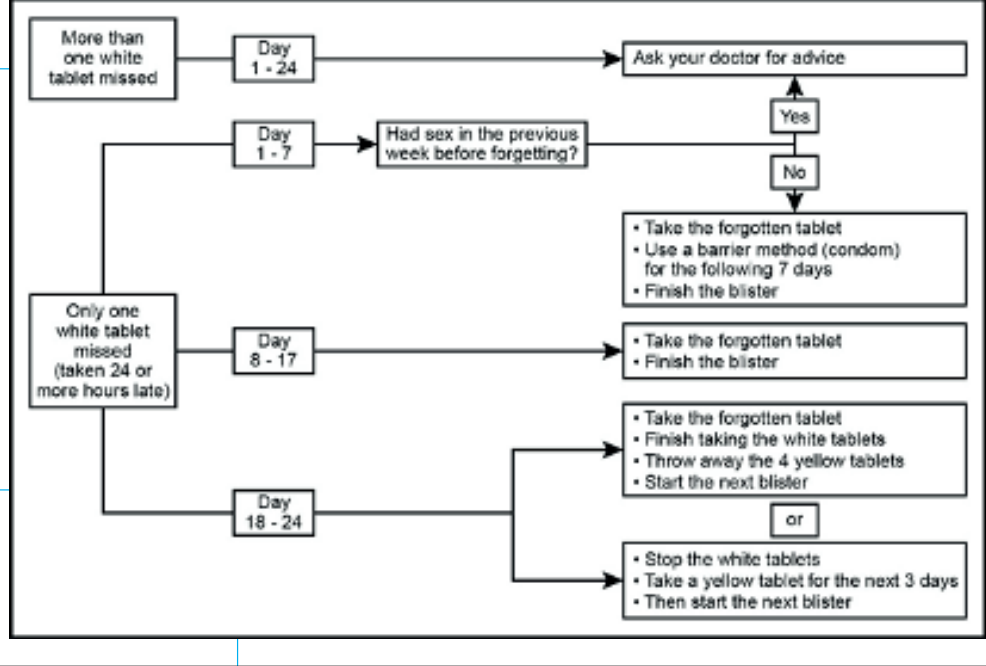
The following advice only refers to forgotten yellow placebo tablets.

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

Picture



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



If you vomit or have severe diarrhoea

If you vomit within 3-4 hours of taking a white active tablet, or you have severe diarrhoea, there is a risk that the active substance in Zoely tablets 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 24 hours* of when you normally take your pill. Take the next tablet at the usual time. If this is not possible or 24 or more hours have passed, you should follow the advice given under "If you forget to take Zoely". If you have severe diarrhoea, please tell your doctor.
The yellow tablets are placebo tablets which do not contain active substances. If you vomit or have severe diarrhoea within 3-4 hours of taking a yellow placebo tablet, the of Zoely protection against pregnancy is maintained.

If you want to delay your period

Even if it is not recommended you can delay your period by missing out taking the yellow placebo tablets from the fourth row and going straight to a new blister of Zoely. You may have 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. Finish the second blister by taking the 4 yellow placebo tablets, and then start with the next (third) blister. **If you are not sure what to do, ask your doctor or pharmacist for advice. If you want to change the starting day of your period**
If you take the tablets according to the instructions, then your period will begin during the placebo days. If you have to change this day, reduce the number of placebo days + when you take the yellow placebo tablets – but never increase them (4 is the maximum). For example, if you start taking the yellow placebo tablets on Friday, and you want to change this to a Tuesday (3 days earlier) you must start a new blister 3 days earlier than usual. You may not have any bleeding during the shortened period of yellow placebo tablet intake. While using the next blister you may have light or menstruation like bleeding on white active tablet-taking days.
If you are not sure what to do, ask your doctor or pharmacist for advice.

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 it is best to wait until you have had a natural period before trying to become pregnant. This will help you to determine when the baby will be due.

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, this medicine 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 (belly)
- 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 sex, 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 via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

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 substances 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: nomegestrol acetate and estradiol
White active film-coated tablets: Each tablet contains 2.5 mg nomegestrol acetate and 1.5 mg estradiol (as hemihydrate).
- 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'), microcrystalline cellulose (E460), crospovidone (E1201), talc (E553b), magnesium stearate (E572) and colloidal anhydrous silica
 - Tablet coat (white active film-coated tablets): Polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol 3350 and talc (E553b)
 - Tablet coat (yellow placebo film-coated tablets): Polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol 3350, talc (E553b), yellow iron oxide (E172) and black iron oxide (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 blisters of 28 film-coated tablets (24 white active film-coated tablets and 4 yellow placebo film-coated tablets) packed in a ply carton. Pack sizes: 28, 84, 168 and 364 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Theramex Ireland Limited
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Manufacturer

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This leaflet was last revised in December 2025.

Zoely 1.5mg / 2.5mg PIL - UK

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