

PACKAGE LEAFLET: INFORMATION FOR THE USER
<b>CILIQUE®</b> 250/35 microgram tablets norgestimate and ethinylestradiol


**Important things to know about the Pill (combined hormonal contraceptives).**

- The Pill is one of the most reliable reversible methods of contraception if used correctly.
- This medicine slightly increases your risk of having a blood clot in the veins and arteries (especially in the first year or when restarting the Pill after 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 2.3 ‘The Pill and blood clots’, ‘How to recognise a blood clot’).

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

- Keep this leaflet. You may need to read it again.
- If you have any questions ask your doctor, family planning nurse or pharmacist.
- 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, family planning nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

- What Cilique is and what it is used for
- What you need to know before you take Cilique
- How to take Cilique
  - A missed pill
- Possible side effects
- How to store Cilique
- Contents of the pack and other information

## 1. WHAT CILIQUE IS AND WHAT IT IS USED FOR

Cilique is a combined hormonal contraceptive pill (‘the Pill’). **You take it to stop getting pregnant.**

This contraceptive contains two types of female sex hormones, oestrogen and progestogen. These hormones prevent an egg being released from your ovaries so you can’t get pregnant. Also, Cilique makes the fluid (mucus) in your cervix thicker which makes it more difficult for sperm to enter the womb. Cilique is a 21-day Pill - you take one each day for 21 days, followed by 7 days when you take no pills.

**The benefits of taking the Pill include:**

- it is one of the most reliable reversible methods of contraception if used correctly
- it doesn’t interrupt sex
- it usually makes your periods regular, lighter and less painful
- it may help with pre-menstrual symptoms and reduce your risk of cancer of the ovary and womb if used for a long time. Cilique will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this. Cilique needs to be taken as directed to prevent pregnancy.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CILIQUE

**General notes**

Before you start using Cilique you should read the information on blood clots in section 2.3. It is particularly important to read the symptoms of a blood clot - see Section 2.3 ‘The Pill and blood clots’.

It’s important that you understand the benefits and risks of taking the Pill before you start taking it, or when deciding whether to carry on taking it. Although the Pill is suitable for most healthy women it isn’t suitable for everyone.

Cilique should not be used by post-menopausal women.

**Tell your doctor** if you have any of the illnesses or risk factors mentioned in this leaflet.

**Before you start taking the Pill**

- Your doctor will ask about you and your family’s medical problems and check your blood pressure. You may also need other checks, such as a breast examination but only if these are necessary for you or you have any special concerns.

**While you’re on the Pill**

- You will need **regular check-ups** with your doctor or family planning nurse, usually when you need another prescription of the Pill.
- You should go for **regular cervical smear tests**.
- Check your breasts** and nipples every month for changes - tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.
- If you need a blood test** tell your doctor that you are taking the Pill, because the Pill can affect the results of some tests.
- If you’re going to have an operation**, make sure your doctor knows about it. You may need to stop taking the Pill about 4-6 weeks before the operation. This is to reduce the risk of a blood clot (see section 2.3). Your doctor will tell you when you can start taking the Pill again.

### 2.1 When you should not use Cilique

You should not use Cilique 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.

**Tell your doctor** or family planning nurse if you have any medical problems or illnesses.

**Do not take Cilique if any of the following applies to you:**

- If you have (or have ever had) a blood clot in a blood vessel of your legs (**deep vein thrombosis, DVT**), your lungs (**pulmonary embolism, 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 2.3 ‘The Pill and blood clots’)
- If you have ever had a **heart attack or stroke**
- If you have (or have ever had) **angina** pectoris (a condition that causes severe chest pain which 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**
  - very high level of **fat in the blood** (cholesterol or triglycerides)
  - a condition called **hyperhomocysteinaemia**
- If you have cancer affected by sex hormones – such as some cancers of the breast or womb lining
- If you have (or have ever had) a type of **migraine** called ‘migraine with aura’
- If you have **breast or liver cancer**
- If you have or have recently had a **severe liver disease**
- If you have hepatitis C and are taking antiviral drug combinations containing paritaprevir/ritonavir, ombitasvir, and dasabuvir (see also in section Other medicines and Cilique).
- If you are **allergic** (hypersensitive) to any of the ingredients in Cilique.
- If you have vaginal bleeding that has not been explained by your doctor.

If you suffer from any of these, or get them for the first time while taking Cilique, contact your doctor as soon as possible. **Do not take Cilique as it may put your health at risk.**

### 2.2 When to take special care with Cilique

**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 (deep vein thrombosis), a blood clot in the lung (pulmonary embolism), a heart attack or a stroke (see Section 2.3 ‘The Pill and blood clots’). For a description of the symptoms of these serious side effects please go to “How to recognise a blood clot”.

**Warnings and precautions**

**Tell your doctor if any of the following conditions applies to you**

If the condition develops, or gets worse while you are using Cilique, you must also tell your doctor. You may still be able to take Cilique but you need to take special care and have check-ups more often:

- If you have problems with your heart, circulation or blood clotting, such as **high blood pressure**, or any of the risks listed in section 2.3 ‘ The Pill and blood clots’. If the high blood pressure is persistent and cannot be controlled, consider an alternative form of birth control. If you do choose to take Cilique, have your blood pressure closely monitored by your doctor.
- If you have **diabetes** without secondary problems
- If you have **liver problems** or **gall bladder disease**
- 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 defence system)
- If you have **porphyria**
- If you have a history of **migraines**
- 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 you are **off your feet** for a long time (see Section 2.3 ‘The Pill and blood clots’)
- If you have had any of the following **problems while pregnant** or during **previous Pill use**, such as itchy skin or blister-like rash, yellowing of skin or eyes, hearing problem, systemic lupus erythematosus (SLE), severe headaches, uncontrollable jerky movements
- 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 Cilique
- 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 **varicose veins**
- If you have **inflammation in the veins under the skin** (superficial thrombophlebitis).

**Psychiatric disorders**

Some women using hormonal contraceptives including Cilique 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.

**Tell your doctor or family planning nurse if any of these applies to you. Also tell them if you get any of these for the first time while taking the Pill**, or if any get worse or come back, because you may need to stop taking Cilique and use another method of contraception, such as condoms.

**Other conditions**

**Chloasma** (yellow-brownish patches on your skin, pigment spots during pregnancy, especially on your face) occasionally occur, especially if you have had a history of it. You may need to keep out of the sun or away from sunbeds (these patches may not completely disappear again).

When additional contraceptive precautions are required you should either avoid having sex or use another method of contraception, such as condoms.

#### 2.3. The Pill and blood clots

Using a Pill such as Cilique 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 an ‘venous thrombosis’, ‘venous thromboembolism’ or VTE)

- in the arteries (referred to as a ‘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 caused by Cilique is small.**

**How to recognise a blood clot**

Seek urgent medical attention if you notice any of the following signs or symptoms.

Do you have any of these signs?	What could you be suffering from?
<ul style="list-style-type: none"><li>swelling of one leg or along a vein in the leg or foot especially with: <ul style="list-style-type: none"><li>pain or tenderness in the leg which may be felt only when standing or walking</li> <li>increased warmth in the affected leg</li> <li>change in colour of the skin on the leg such as turning pale, red or blue.</li></ul></li></ul>	Deep vein thrombosis (DVT) (blood clot in the large vein of the leg)
<ul style="list-style-type: none"><li>sudden unexplained breathlessness or rapid breathing</li> <li>sudden cough without an obvious cause, which may bring up blood</li> <li>sharp chest pain which may increase with deep breathing</li> <li>severe light headedness or dizziness</li> <li>rapid or irregular heartbeat</li> <li>severe pain in your stomach</li></ul> <p>If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a ‘common cold’).</p>	Pulmonary embolism (PE) (blood clot in the lungs)
<p>symptoms most commonly in one eye:</p> <ul style="list-style-type: none"><li>immediate loss of vision or</li> <li>painless blurring of vision which can become a loss of vision.</li></ul>	Retinal vein thrombosis (blood clot in the eye)
<ul style="list-style-type: none"><li>chest pain or discomfort, pressure,</li> <li>heaviness</li> <li>sensation of squeezing or fullness in the chest, arm or below the breastbone</li> <li>fullness, indigestion or choking feeling</li> <li>upper body discomfort spreading out to the back, jaw, throat, arm and stomach</li> <li>sweating, nausea, vomiting or dizziness</li> <li>extreme weakness, anxiety, or shortness of breath</li> <li>rapid or irregular heartbeats.</li></ul>	Heart attack
<ul style="list-style-type: none"><li>sudden weakness or numbness of the face, arm or leg, especially on one side of the body</li> <li>sudden confusion, trouble speaking or understanding</li> <li>sudden trouble seeing in one or both eyes</li> <li>sudden trouble walking, dizziness, loss of balance or coordination</li> <li>sudden, severe or prolonged headache with no known cause</li> <li>loss of consciousness or fainting with or without seizure.</li></ul>	Stroke (blood clot in the brain)
<ul style="list-style-type: none"><li>swelling and slight blue discolouration of an extremity such as hands and feet</li> <li>severe pain in your stomach (acute abdomen).</li></ul>	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 the Pill for the first time. The risk may also be higher if you restart taking the Pill (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 the Pill. When you stop using Cilique, 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 Pill you are taking. The overall risk of a blood clot in the leg or lung (DVT or PE) with Cilique 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 **taking a Pill** containing levonorgestrel or norethisterone, or norgestimate such as Cilique, about **5-7** will develop a blood clot in a year.
- 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).

	<b>Risk of developing a blood clot in a year</b>
Women who are <b>not using</b> a combined hormonal Pill/patch/ring and are not pregnant	About 2 out of 10,000 women
Women using a Pill containing <b>levonorgestrel, norethisterone or norgestimate</b>	About 5-7 out of 10,000 women
Women using Cilique	About 5-7 out of 10,000 women

**Factors that increase your risk of a blood clot in a vein**

The risk of a blood clot with Cilique is small but some conditions will increase the risk. Your risk is higher:

- if you are **very overweight** (body mass index or BMI over 30 kg/m<sup>2</sup>)
- if one of your immediate family has had a **blood clot** in the leg, lung or other organ at a young age (such as, below the age of about 50 years old). 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 Cilique may need to be stopped for several weeks before surgery or while you are less mobile. If you need to stop Cilique 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 (for longer than 4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other risk factors listed.

**It is important to tell your doctor** if any of these risk factors apply to you, even if you are unsure. Your doctor may decide that Cilique needs to be stopped. If any of the above conditions change while you are using Cilique, for example a close family member has 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 Cilique is very small but can increase:

- with **increasing age** (particularly above about 35 years old)
- if you smoke**. When using a Pill like Cilique 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 **has 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.

**Tell your doctor** if any of these risk factors applies to you. If any of the above conditions change while you are using Cilique, for example you start smoking, a close family member has a thrombosis for no known reason, or you gain a lot of weight, tell your doctor. Taking the Pill may add to these risks so Cilique may not be suitable for you.

### 2.4 The Pill and cancer

The Pill reduces your risk of cancer of the ovary and womb if used for a long time. However, it also seems to slightly increase your risk of **cancer of the cervix** - although this may be due to having sex without a condom, rather than the Pill. All women should have regular **smear tests**.

If you have **breast cancer**, or have had it in the past, you should not take the Pill. The Pill slightly increases your risk of breast cancer. This risk goes up the longer you’re on the Pill, but returns to normal within about 10 years of stopping it. Because breast cancer is rare in women under the age of 40, the extra cases of breast cancer in current and recent Pill users are small.

**Your risk of breast cancer is higher:**

- as you get older
- if you have a close relative (mother, sister or grandmother) who has had breast cancer
- if you are seriously overweight.

**See a doctor as soon as possible if you notice any changes in your breasts**, such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.

Taking the Pill has also been linked to liver diseases, such as jaundice and non-cancer liver tumours, but this is rare. Very rarely, the Pill has also been linked with some forms of liver cancer in women who have taken it for a long time.

**See a doctor as soon as possible if you get severe pain in your stomach, or yellow skin or eyes** (jaundice). You may need to stop taking Cilique.

#### 2.5 Other medicines and Cilique

If you ever need to take another medicine at the same time as being on the Pill, always tell your doctor, pharmacist or dentist that you’re taking Cilique. Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

**Some medicines can stop Cilique from working properly** - for example:

- some medicines used to treat epilepsy** (such as topiramate, carbamazepine, phenytoin, fosphenytoin, oxcarbazepine, felbamate, primidone, eslicarbazepine acetate, rufinamide)
- bosentan** (for high blood pressure in the blood vessels of the lungs)
- certain medicines for tuberculosis such as **rifampicin** and **rifabutin**



- anti-HIV medicines**
- boceprevir** and **telaprevir** (for treatment of Hepatitis C infections)
- aprepitant** and **fosaprepitant** (for prevention of nausea and vomiting caused by certain cancer drug treatment)
- griseofulvin (**for fungal infections**)
- modafinil** (for excessive daytime sleepiness)
- certain sedatives** (called ‘barbiturates’)
- St. John’s Wort** (a herbal remedy)
- metoclopramide** (to increase movement through the gut)
- charcoal**
- colesevelam** (to treat high cholesterol levels)
- paracetamol** (for pain and fever relief)
- etoricoxib** (to help with pain and inflammation of arthritis)
- vitamin C** (ascorbic acid)
- drugs for fungal infections** such as itraconazole, ketoconazole, voriconazole, fluconazole
- atorvastatin** and **rosuvastatin** (for high cholesterol levels).

If you do need to take one of these medicines, Cilique may not be suitable for you or you may need to use extra contraception (such as a condom or diaphragm) for a while. Your doctor, pharmacist or dentist can tell you if this is necessary and for how long.

**Cilique can also affect other medicines** - for example:

- ciclosporin** (to prevent transplant rejection and for rheumatoid arthritis or some skin problems)
- omeprazole** (to reduce production of acid in the stomach)
- lamotrigine** (for epilepsy)
- prednisolone** (a steroid to reduce inflammation)
- selegiline** (for Parkinson’s disease)
- theophylline** (for asthma, bronchitis and emphysema)
- voriconazole** (for fungal infections)
- tizanidine** (used to relax muscles)
- paracetamol** and **aspirin** (for pain and fever relief)
- clofibric acid** (for high cholesterol levels)
- morphine** (a strong painkiller)
- temazepam** (for anxiety)
- insulin** or other **anti-diabetic drugs**.

Do not take Cilique if you have Hepatitis C and are taking antiviral drug combinations containing ombitascir/paritaprevir/ritonavir and dasabuvir as this may cause increases in liver function blood test results (increase in ALT liver enzyme). Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicinal products. Cilique can be restarted approximately 2 weeks after completion of this treatment. See section ‘‘Do not take Cilique’’.

Cilique may also affect the results of certain blood and urine tests. Tell your doctor that you are taking Cilique before you have any such tests.

### 2.6 Taking Cilique with food and drink

Do not drink grapefruit juice while taking Cilique.

### 2.7 Pregnancy and breast-feeding

**Do not start to use Cilique** if you are pregnant. If you think you might be pregnant while taking Cilique, do a pregnancy test to confirm that you are before you stop taking it.

**If you are breast-feeding**, your doctor or family planning nurse may advise you not to take Cilique. Talk to them about alternative contraception. Breast- feeding may not stop you getting pregnant.

### 2.8 Driving and using machines

Cilique has no known effect on the ability to drive or use machines.

### 2.9 Important information about some of the ingredients of Cilique

Cilique contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before using Cilique.

## 3. HOW TO TAKE CILIQUE

#### 3.1 How to take it

To prevent pregnancy, always take Cilique as described below. Check with your doctor or family planning nurse if you are not sure.

#### Take Cilique every day for 21 days

Cilique comes in a strip of 21 pills, each marked with a day of the week.

- Take your pill at the same time every day.
- Start by taking a pill marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one pill each day.
- Swallow each pill whole, with water if necessary. Do not chew the pill.

#### Then have seven pill-free days

After you have taken all 21 pills in the strip, you have seven days when you take no pills. So if you take the last pill of one pack on a Friday, you will take the first pill of your next pack on the Saturday of the following week.

Within a few days of taking the last pill from the strip, you should have a withdrawal bleed like a period. This bleed may not have finished when it is time to start your next strip of pills. You don’t need to use extra contraception during these seven pill-free days - as long as you have taken your pills correctly and start the next strip of pills on time.

#### Then start your next strip

Start taking your next strip of Cilique after the seven pill-free days - even if you are still bleeding. Always start the new strip on time.

As long as you take Cilique correctly, you will always start each new strip on the same day of the week.

#### 3.2 Starting Cilique

**As a new user or starting the Pill again after a break**
**Either** take your first Cilique pill on the first day of your next period. This way, you will have contraceptive protection with your first pill.

**Or** if your period has already begun, start taking Cilique up to day 5 (counting the first day of your period as day 1) whether or not your bleeding has stopped. You must also use extra contraception, such as condoms, until you have taken the first seven pills correctly.

#### Changing from a combination hormonal contraceptive, or combination contraceptive vaginal ring or patch

You can start Cilique preferably on the day after the last active tablet (the last tablet containing the active substances) of your previous pill, but at the latest on the day after the tablet-free days of your previous pill (or after the last inactive tablet of your previous pill). When changing from a combination contraceptive vaginal ring or patch, follow the advice of your doctor.

#### Changing from a progestogen-only-method (progestogen-only pill, injection, implant or a progestogen-releasing intrauterine system (IUS)

You may switch any day from the progestogen-only pill (from an implant or an IUS on the day of its removal, from an injectable when the next injection would be due) but in all of these cases use extra protective measures (for example, a condom) for the first 7 days of tablet-taking.

#### Starting Cilique after a miscarriage or abortion

If you have had a miscarriage or an abortion, your doctor may tell you to start taking Cilique straight away. This means that you will have contraceptive protection with your first pill.

#### Contraception after having a baby

If you have just had a baby, you are more at risk of blood clots (see Section 2.3 ‘‘The Pill and blood clots’’). Ask your doctor when you can start taking Cilique again. If it is 21 days after the birth, you will have contraceptive protection with your first pill.

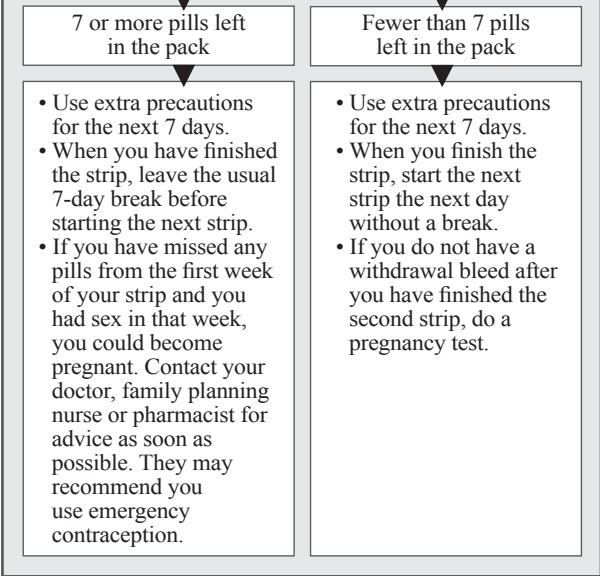
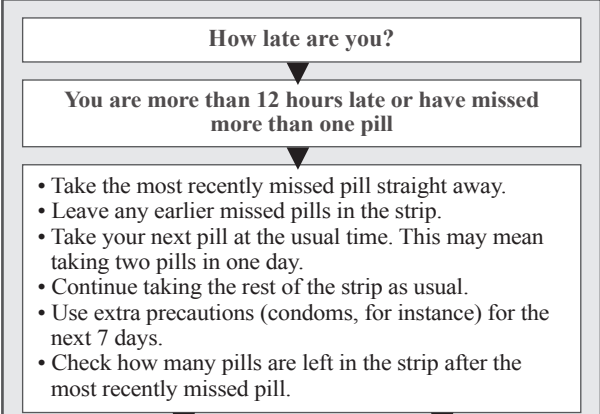
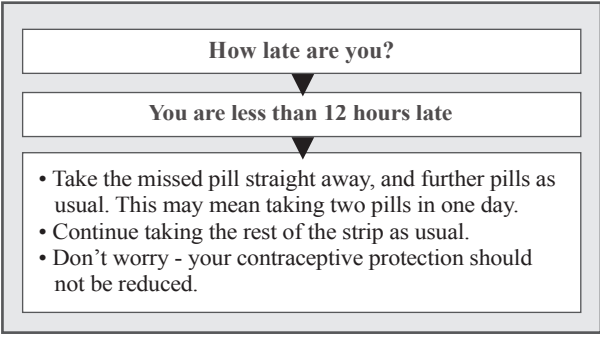
If you have sex before you start taking Cilique or before your first period, wait until your period starts before you take Cilique and then take it on the first day of bleeding.

#### 3.3 A missed pill

Missing pills or starting a strip late may make your pill less

effective. The chance of pregnancy after missing pills depends on **when** pills are missed and **how many** pills are missed. Missing one pill anywhere in your strip or starting a new strip one day late is not a problem. Missing **more than one** or starting a strip **more than one day late** may affect your contraceptive cover.

It is more risky to start a strip late and miss more than one pill.



If you have missed any of the pills in a strip, and you do not bleed in the first pill-free break, you may be pregnant. Contact your doctor or family planning clinic, or do a pregnancy test yourself.

**If you start a new strip of pills late**, or make your ‘week off’ longer than eight days, you may not be protected from pregnancy. If you had sex in the last seven days, ask your doctor, family planning nurse or pharmacist for advice. You may need to consider emergency contraception. You should also use extra contraception, such as a condom, for seven days.

#### 3.4 A lost pill

If you lose a pill, just take a pill from a spare strip. Then take all the other pills from your current strip as usual. You can then keep the opened spare strip in case you lose any more pills.

#### 3.5 If you are sick or have diarrhoea

If you are sick or have very bad diarrhoea, your body may not get its usual dose of hormones from that pill. If you have been sick **within 2 hours of taking Cilique**, just take a pill from a spare strip. Carry on taking your pills as normal if you can. You

won’t need to use extra contraception.

If you are still sick or have diarrhoea for **more than 1 day**, follow the instructions for a missed pill - see section 3.3, A missed pill.

**Talk to your doctor if your stomach upset carries on or gets worse.** He or she may recommend another form of contraception.

#### 3.6 Missed a period - could you be pregnant?

Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you have taken your pills correctly. Start your next strip at the normal time. If you think that you might have put yourself at risk of pregnancy (for example, by missing pills or taking other medicines), or if you miss a second bleed, you should do a pregnancy test. You can buy these from the chemist or get a free test at your family planning clinic or doctor’s surgery. If you are pregnant, stop taking Cilique and see your doctor.

#### 3.7 Taking more than one pill should not cause harm

It is unlikely that taking more than one pill will do you any harm, but you may feel sick, vomit or have some vaginal bleeding. Talk to your doctor if you have any of these symptoms.

#### 3.8 You can delay a period

If you want to delay having a period, finish the strip of pills you are taking. Start the next strip the next day without a break. Pill taking should then continue as usual.

When you use the second strip, you may have some unexpected bleeding or spotting on the days that you take the pill, but don’t worry. Take the next strip after the usual 7 day break even if you are still bleeding or spotting.

#### 3.9 When you want to get pregnant

If you are planning a baby, it’s best to use another method of contraception after stopping Cilique until you have had a proper period. Your doctor or midwife relies on the date of your last natural period to tell you when your baby is due. The Pill may reduce the levels of folic acid in the blood. Talk to your doctor, nurse or pharmacist as this could be important if you get pregnant straight after stopping the Pill.

## 4. POSSIBLE SIDE EFFECTS

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

**Tell your doctor, pharmacist or family planning nurse** if you get any side effect particularly if they are severe and persistent, or you have any change in your health which you think may be due to Cilique.

#### 4.1 Serious side effects - see a doctor straight away

- Harmful blood clots in a vein or artery** (frequency not known) for example:
  - in a leg or foot (DVT)
  - in a lung (PE)
- heart attack
- stroke
- mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA)
- blood clots in stomach/intestines, kidneys or eye
- blood clots in the liver, which can cause an enlarged liver, pain and swelling (Budd – Chiari syndrome).

An increased risk of blood clots in your veins (venous thromboembolism, VTE) or arteries (arterial thromboembolism, ATE) is present for all women taking the Pill. For more detailed information on the different risks from taking the Pill, please see Section 2 ‘‘Make sure Cilique is OK for you’’. The chance of having a blood clot may be higher if you have any other conditions that increase this risk (see Section 2.3 ‘‘The Pill and blood clots’’ for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot).

**Breast cancer** (frequency not known) signs include:

- dimpling** of the skin
- changes in the nipple**
- any **lumps** you can see or feel.

**Severe liver problems** (rare - may affect up to 1 in 1,000 people) signs include:

- severe **pain** in your **upper abdomen**
- yellow skin or eyes** (jaundice).

**Other serious side effects include:**

- increased blood pressure** (uncommon - may affect up to 1 in 100 people)
- fits (convulsions)** (frequency not known)
- hives (urticaria)** (uncommon - may affect up to 1 in 100 people), **swelling** of the face, lips, mouth, tongue or throat which may cause **difficulty in swallowing or breathing**. These may be signs of **allergy**.

**If you think you may have any of these, see a doctor straight away.** You may need to stop taking Cilique.

#### 4.2 Other possible side effects - tell your doctor

- Very common** (may affect more than 1 in 10 people)
- Headache** (but if severe, unusual or long lasting, see a doctor as soon as possible)
- Stomach problems** such as nausea, vomiting and diarrhoea
- Bleeding and spotting between your periods** for the first few months (though this usually stops when your body adjusts to Cilique) - see section 4.3, Bleeding between periods should not last long
- Painful or unusual periods.**

- Common** (may affect up to 1 in 10 people)
- Migraine** (see a doctor as soon as possible if this is your first migraine or it’s worse than usual)
- Swollen hands, ankles or feet**
- Depression; mood changes; feeling nervous** or dizzy
- Difficulty sleeping** (insomnia)
- Stomach ache and bloating; constipation; wind**
- Acne; rash**
- Muscle spasms; pain in the legs, arms and back**
- Painful breasts**
- Urinary tract infections** (pain on passing urine)
- Vaginal infections such as **thrush**
- Vaginal discharge**
- No menstrual periods**
- Feeling **weak**
- Weight gain.**

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

- Breast problems**, such as fuller breasts; producing fluid from the nipples
- Abnormal cells** in the **cervix** (identified by a smear test)
- Feeling **anxious** or faint; **tingling sensation** or **numbness**
- Changes in **skin colour**
- Skin problems** such as **redness** and **itchiness**
- Hair thinning** (alopecia), **excessive hair growth**
- Changes in appetite**
- Weight may vary**
- Change in sex drive**
- Dry eyes**
- Changes in vision**
- Palpitations** (feeling your heart beat)
- Hot flushes**
- Muscle pain**
- Vaginal dryness**
- Ovarian cysts** (may cause pain and swelling of the abdomen, changes in periods).

**Rare** (may affect up to 1 in 1,000 people)

- Lumpy breasts**
- Loss of sex drive**
- Feeling **giddy**
- Faster **heart beat**
- Pancreatitis** (inflammation of the pancreas, which causes severe pain in the abdomen and back)
- Increased **sweating**
- Sensitivity to **light**.

- Not known:** frequency cannot be estimated from the available data
- Reduced amount of breast milk (if breast feeding)**
- Contact lenses** may feel uncomfortable
- Red painful lumpy swellings** on the legs
- Changes in **fat levels** in the blood (seen by blood tests)
- Night sweats.**

#### 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:
**U.K.:** Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

**Ireland:** HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

**4.3 Bleeding between periods should not last long**
Usually you should only have a withdrawal bleed like a period during the seven pill-free days. However, a few women have a little unexpected bleeding or spotting while they are taking Cilique, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking Cilique as usual. The problem should disappear after the first few strips.

You may also have unexpected bleeding if you are not taking your pills regularly, so try to take your pill at the same time every day. Also, unexpected bleeding can sometimes be caused by other medicines.

**Make an appointment to see your doctor** if you get breakthrough bleeding or spotting that:

- carries on for more than the first few months
- starts after you’ve been taking Cilique for a while
- carries on even after you’ve stopped taking Cilique.

### 5. HOW TO STORE CILIQUE

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

Do not store above 25°C. Store in the original packaging to protect from light.

Do not use Cilique after the expiry date shown on the strip. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater of household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

**What Cilique contains:**

The active substances are 250 micrograms of norgestimate and 35 micrograms of ethinyloestradiol.

Cilique also contains the other ingredients: maize starch, lactose, magnesium stearate (E470b), indigo carmine (E132).

The tablets are blue, round and biconvex.

Each pack contains 3 or 6 blister strips each containing 21 tablets.

Not all pack sizes may be marketed.

<b>Marketing Authorisation Holder and Manufacturer</b>
<b>Marketing Authorisation Holder</b> Consilient Health Ltd., 5th floor, Beaux Lane House, Mercer Street Lower, Dublin 2, Ireland
<b>Manufacturer</b> CYNDEA PHARMA, S.L. Polígono Industrial Emiliano Revilla Sanz. Avenida de Ágreda, 31, Olvega, 42110 Soria

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