

PACKAGE LEAFLET: INFORMATION FOR THE USER

Cilest[®] 250/35 microgram tablets

Norgestimate/ethinylestradiol

Cilest is a registered trademark

Important things to know about the Pill (combined hormonal contraceptive):

- It is one of the most reliable reversible methods of contraception if used correctly
- It slightly increases the risk of having a blood clot in the veins and arteries, especially in the first year or when restarting a Pill following a break of 4 or more weeks
- Please be alert and see your doctor if you think you may have symptoms of a blood clot (see 'How to recognise a blood clot' in Section 2.3 'The Pill and blood clots')

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 further questions, ask your doctor 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1 What Cilest is and what it is used for**
- 2 What you need to know before you take Cilest**
- 3 How to Take Cilest**
 - 3.3 A missed pill**
- 4 Possible side effects**
- 5 How to store Cilest**
- 6 Contents of the pack and other information**

1 What Cilest is and what it is used for

The name of your medicine is Cilest 250/35 microgram tablets. It is called 'Cilest' in this leaflet.

Cilest is a combined hormonal contraceptive pill ('the Pill'). **You take it to stop getting pregnant.**

This low-dose 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 Cilest makes the fluid (mucus) in your cervix thicker, making it more difficult for sperm to enter the womb, and changes the lining of the womb so that fertilised eggs are unable to grow there.

Cilest 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

Cilest will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this.

Cilest needs to be taken as directed to prevent pregnancy.

2 What you need to know before you take Cilest

General notes

Before you start taking Cilest you should read the information on blood clots (thrombosis) in section 2. It is particularly important to read the information on blood clots in section 2.3 below and know what the symptoms are.

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.

→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 or a smear test

While you're on the Pill

- You will need **regular check-ups** with your doctor (at least twice a year), 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 will need to stop taking the Pill about 6 weeks before the operation. This is to reduce the risk of a blood clot (see section 2.1). Your doctor will tell you when you can start taking the Pill again

2.1 When you should not take Cilest

You should not take Cilest 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 if you have any medical problems or illnesses.

Do not take Cilest if any of the following applies to you. Taking Cilest may put your health at risk.

- 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** (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 are **pregnant** or might be pregnant, or if you are **breast-feeding**
 - If you have **cancer** affected by sex hormones – such as some **cancers of the breast or womb lining**
 - If you have **thickening of the womb lining**
 - If you have **vaginal bleeding** that has not been explained by your doctor
 - If you have (or have ever had) a type of **migraine** called ‘migraine with **aura**’
 - If you **smoke** more than 15 cigarettes a day and are 35 years old or over
 - If you have a blood problem called ‘**porphyria**’
 - If you have **severe liver disease**, including liver cancer, cirrhosis, hepatitis, jaundice, Dubin-Johnson syndrome or Rotor syndrome
 - If you have **gallstones**
 - If you have **sickle cell anaemia**
 - If you have had any of the following **problems while pregnant** or during previous Pill use:
 - itching of the whole body (*pruritus*)
 - jaundice which was not caused by infection
 - a blister-like rash, called *herpes gestationis*
 - a hearing problem called otosclerosis
 - If you have the disease **systemic lupus erythematosus** (SLE)
 - If you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir (see also in section Other medicines and Cilest).
 - If you are **allergic** (hypersensitive) to any of the ingredients in Cilest.
- If you suffer from any of these, or get them for the first time while taking Cilest, contact your doctor as soon as possible. **Do not take Cilest as it may put your health at risk.**

2.2 When to take special care with Cilest

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' (thrombosis) above.

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 Cilest, you must also tell your doctor. You may still be able to take Cilest but you need to take special care and have check-ups more often.

- 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 **haemolytic uraemic syndrome** (HUS, a disorder of blood clotting causing failure of the kidneys)
- 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 **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 Cilest
- If you have an **inflammation in the veins** under the skin (superficial thrombophlebitis)
- If you have **varicose veins**
- 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 Cilest, have your blood pressure closely monitored by your doctor
- If you have **diabetes**
- If you have any **gynaecological problems**, such as **fibroids** or **endometriosis**
- If there is a **family history of breast cancer**, or past history of **lumpy breasts**
- If you have **asthma**
- If you have or have ever had **kidney or liver problems**
- If you have had **gallstones** in the past

- If you have had **depression**
- If you have had **epilepsy** or **migraines**
- If you have a **hearing problem** called otosclerosis
- If you have **multiple sclerosis** (MS)
- If you have painful **muscle spasms, twitching or cramps** (called tetany)
- If you have St. Vitus' dance (also called Sydenham's chorea) that causes **jerky, uncontrollable movements** of the face, arms or legs.

→ **Tell your doctor 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 Cilest.

Psychiatric disorders:

Some women using hormonal contraceptives including Cilest 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.

Other things to know:

- When you stop taking Cilest, you may notice your periods take some time to start again or are irregular.
- If you have had hepatitis, do not take Cilest for at least 3 months after your liver function tests have returned to normal.
- If you are over 35 years old, talk to your doctor about whether Cilest is still the best contraception for you.
- If you have brown patches on your face or body (chloasma) or have a history of them as you may need to keep out of the sun or away from sunbeds (these patches may not completely disappear again)

Stop taking Cilest straight away and tell your doctor if you:

- have symptoms of a blood clot (see 'How to recognise a blood clot' in section 2.3 'The Pill and blood clots' above)
- have chest pain and tightness in the chest, shortness of breath or coughing for no apparent reason
- are to have an operation. Cilest must not be used for at least 6 weeks before an operation
- have to stay in bed or remain off your feet for a long time
- know or suspect that you may be pregnant
- develop:
 - sudden problems with eyesight, hearing or speech
 - migraines or your existing migraines worsen or you have unusual or severe headaches
 - yellow skin or eyes (jaundice)
 - other liver problems such as hepatitis or existing problems become worse
 - itching all over the body
 - epileptic fits (convulsions) or your existing epilepsy becomes worse
 - high blood pressure

- severe depression
- unexpected stomach pains

See also section 4.1 Serious side effects.

2.3 The Pill and blood clots

Using a Pill such as Cilest 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 Cilest is small.

How to recognise a blood clot

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

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none"> • swelling of one leg or along a vein in the leg or foot especially when accompanied by: <ul style="list-style-type: none"> • pain or tenderness in the leg which may be felt only when standing or walking • increased warmth in the affected leg • change in colour of the skin on the leg such as turning pale, red or blue. 	<p>Deep vein thrombosis</p>
<ul style="list-style-type: none"> • sudden unexplained breathlessness or rapid breathing • sudden cough without an obvious cause, which may bring up blood • sharp chest pain which may increase with deep breathing • severe light headedness or dizziness • rapid or irregular heartbeat • severe pain in your stomach. <p>If you are unsure, talk to a doctor as some of these symptoms such as coughing or being</p>	<p>Pulmonary embolism</p>

<p>short of breath may be mistaken for a milder condition such as a respiratory tract infection (like a common cold).</p>	
<p>symptoms most commonly in one eye:</p> <ul style="list-style-type: none"> ● immediate loss of vision or ● painless blurring of vision which can progress to loss of vision. 	<p>Retinal vein thrombosis (blood clot in the eye)</p>
<ul style="list-style-type: none"> ● chest pain, discomfort, pressure, heaviness ● sensation of squeezing or fullness in the chest, arm or below the breastbone ● fullness, indigestion or choking feeling ● upper body discomfort radiating to the back, jaw, throat, arm and stomach ● sweating, nausea, vomiting or dizziness ● extreme weakness, anxiety, or shortness of breath ● rapid or irregular heartbeats. 	<p>Heart attack</p>
<ul style="list-style-type: none"> ● sudden weakness or numbness of the face, arm or leg, especially on one side of the body ● sudden confusion, trouble speaking or understanding ● sudden trouble seeing in one or both eyes ● sudden trouble walking, dizziness, loss of balance or coordination ● sudden, severe or prolonged headache with no known cause ● loss of consciousness or fainting with or without seizure. <p>Sometimes the symptoms of a stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.</p>	<p>Stroke</p>
<ul style="list-style-type: none"> ● swelling and slight blue discolouration of an extremity ● severe pain in your stomach (acute abdomen) 	<p>Blood clots blocking other blood vessels</p>

Blood clots in a vein

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

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

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

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

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

When you stop using Cilest, 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 the combined hormonal contraceptive you are taking.

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

- Out of 10,000 women who are **not using any combined hormonal contraceptive** and are not pregnant, about **2** will develop a blood clot in a year.
- Out of 10,000 women **who are using a combined hormonal contraceptive** that contains levonorgestrel or norethisterone or norgestimate such as Cilest, 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)

	Risk of developing a blood clot in a year
Women who are not using a combined hormonal contraceptive Pill/patch/ring and are not pregnant	About 2 out of 10,000 women
Women using a combined hormonal contraceptive containing	About 5-7 out of 10,000 women

levonorgestrel, norethisterone or norgestimate	
Women using Cilest	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 Cilest 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/m²)**
- if one of your immediate family has had a **blood clot** in the leg, lung or other organ at a young age (below 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 Cilest may need to be stopped for several weeks before surgery or while you are less mobile. If you need to stop Cilest ask your doctor when you can start using it again
- as you get **older** (particularly above about 35 years old)
- 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 conditions applies to you, even if you are unsure. Your doctor may decide that Cilest needs to be stopped. If any of the above conditions change while you are using Cilest, 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 Cilest is very small but can increase:

- with increasing age (particularly above about 35 years old)
- if you **smoke**. When using a Pill like Cilest 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** that is not controlled through treatment
- 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 Cilest, 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 this risk so Cilest 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 older you are. The length of time you are on the Pill is not so important. 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:

- 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 Cilest.

2.5 Other medicines and Cilest

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 Cilest. Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

Some medicines can stop Cilest 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**
- **aprepitant and fosaprepitant** (for prevention of nausea and vomiting caused by certain cancer drug treatments)
- **griseofulvin** (for fungal infections)
- **certain sedatives** (called 'barbiturates')
- **modafinil** (for excessive daytime sleepiness)
- **St. John's Wort** (a herbal remedy for depression)
- **anti-HIV medicines**
- **boceprevir and telaprevir** (for treatment of Hepatitis C infections)
- **colesevelam** (to treat high cholesterol levels)
- **paracetamol** (for pain and fever relief)
- **etoricoxib** (to help with pain and inflammation of arthritis)
- **metoclopramide** (to increase movement through the gut)
- **charcoal** (to reduce wind, bloating and indigestion)
- **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, Cilest 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.

Cilest can also affect how well other medicines work - for example:

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

Do not take Cilest if you have Hepatitis C and are taking the medicinal products containing ombitasvir/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. Cilest can be restarted approximately 2 weeks after completion of this treatment. See section "Do not take Cilest".

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

2.6 Taking Cilest with food and drink

Do not drink grapefruit juice while taking Cilest.

2.7 Pregnancy and breast-feeding

Do not take Cilest if you are pregnant. If you think you might be pregnant, do a pregnancy test to confirm that you are pregnant before you stop taking Cilest.

Do not take Cilest if you are breast-feeding as this may affect your breast milk. Talk to your doctor about alternative contraception. Breast-feeding will not stop you getting pregnant.

2.8 Driving and using machines

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

2.9 Important information about some of the ingredients of Cilest

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

3 How to take Cilest

3.1 How to take it

To prevent pregnancy, always take Cilest as described below. Check with your doctor if you are not sure. While you are taking Cilest, see your doctor regularly, at least twice a year.

Take Cilest every day for 21 days

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

- Take your pill at about 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 Cilest after the seven pill-free days – even if you are still bleeding. Always start the new strip on time.

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

3.2 Starting Cilest

As a new user or starting the Pill again after a break

Either take your first Cilest pill on the first day of your next period. (By starting in this way, you will have contraceptive protection with your first pill.)

Or if your period has already begun, start taking Cilest 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 to Cilest from another contraceptive Pill

- **If you are currently taking a 21-day Pill**, start Cilest the next day after the end of the previous strip. You will have contraceptive protection with your first Cilest pill. You may have a light bleed while you are taking the pills or you will not have a bleed until after your first strip of Cilest.
- **If you are taking a 28-day Pill** (Every Day or ED pack), start taking Cilest the day after your last active pill (after the first 21 pills). Throw away the remaining pills from your ED pack. You will have contraceptive protection with your first Cilest pill. You may have a light bleed while you are taking the pills or you will not have a bleed until after your first strip of Cilest.
- **If you are taking a progestogen-only Pill** (POP or 'mini Pill')
 - start Cilest on the first day of bleeding, even if you have already taken the progestogen-only Pill for that day. You will have contraceptive protection with your first Cilest pill.
 - if you do not have a bleed, start taking Cilest on the day after the last progestogen-only Pill in your pack. You should use extra contraception, such as a condom, for seven days.

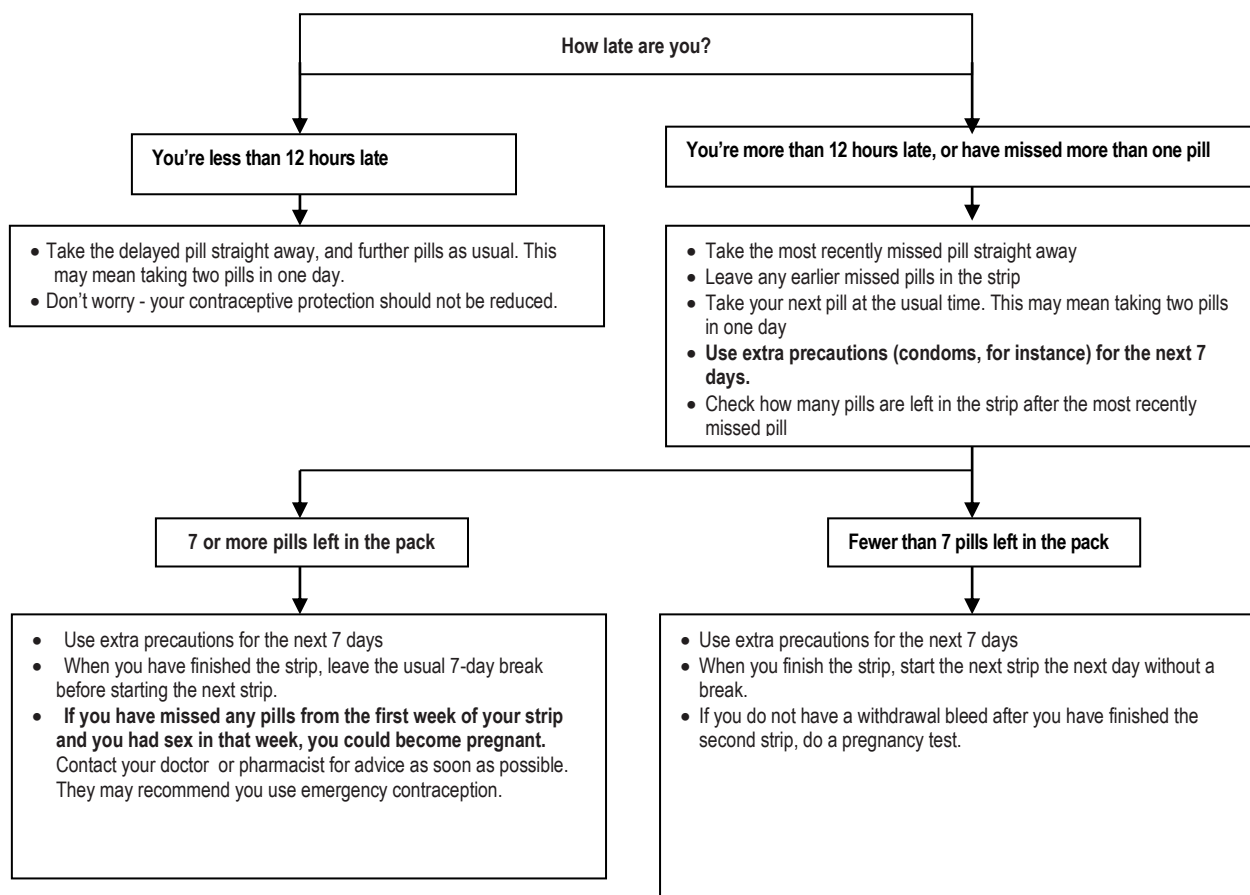
Starting Cilest after a miscarriage

If you have had a miscarriage at or before 20 weeks of the pregnancy, your doctor may tell you to start taking Cilest straight away. This means that you will have contraceptive protection with your first pill. Ask your doctor about alternative contraception if you are not starting Cilest immediately.

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 for advice about contraception.

3.3 A missed 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 do a pregnancy test yourself.

If you start a new strip of pills late, or make your 'week off' longer than seven days, you may not be protected from pregnancy. If you had sex in the last seven days, ask your doctor 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 your symptoms start **within 3 hours of taking Cilest** or severe diarrhoea carries on **for more than 24 hours**:

- use extra contraception for as long as you are ill and for 7 days after you are better
- keep taking Cilest if you can
- if this means the strip is empty before you have been able to take 7 pills without problems, start a new strip straight away without the usual 7 day break.

If you do not have a withdrawal bleed after you have finished the second strip, do a pregnancy test.

→**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. You should do a pregnancy test before you are due to start the next strip. You can get these from the chemist or your doctor's surgery. If you are pregnant, do not start the next strip of Cilest and see your doctor. If you are not pregnant start your next strip at the normal time.

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 Cilest 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. However, it will not cause you or the baby any harm if you get pregnant straight away.

4 Possible side effects

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

→**Tell your doctor or pharmacist** if you get any side effect, particularly if they are severe and persistent, or you have any change in your health that you think may be due to Cilest.

4.1 Serious side effects – stop taking Cilest and 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 combined oral contraceptives. For more detailed information on the different risks from taking combined oral contraceptives, please see Section 2 'What you need to know before you take Cilest'. 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 (but not all lumps are cancerous)

Cancer of the cervix (uncommon - affects fewer than 1 in 100 patients)

Signs include:

- **vaginal discharge** that smells and contains blood
- unusual **vaginal bleeding**
- **pelvic pain**
- **painful sex**

Severe liver problems (rare - affects fewer than 1 in 1000 patients)

Signs include:

- severe **pain** in your **upper abdomen**
- **dark urine or pale stools**
- **yellow skin or eyes** (jaundice)

Other serious side effects include:

- sudden swelling of the face or throat which may cause difficulty in swallowing or breathing, or hives (also known as nettle rash or urticaria). These may be signs of an allergic reaction (uncommon - affects fewer than 1 in 100 patients)
- increased blood pressure (uncommon - affects fewer than 1 in 100 patients)

→If you think you may have any of these, see a doctor straight away.

You may need to stop taking Cilest.

4.2 Other possible side effects – tell your doctor

Very common (affects 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 feeling sick (nausea), being sick (vomiting) and diarrhoea
- **Painful periods, abnormal periods** including bleeding and spotting between periods – see section 4.3, Bleeding between periods should not last long

Common (affects more than 1 in 100 people)

- **Migraine** (see a doctor as soon as possible if this is your first migraine or it's worse than usual)
- **Feeling dizzy or weak**
- **Weight gain**
- **Depression** (but if severe, unusual or long lasting, see a doctor as soon as possible)
- **Mood changes, feeling nervous or difficulty sleeping** (insomnia)
- **Gynaecological problems**
 - vaginal infections
 - discharge from the vagina
 - no periods
- **Urinary tract infection** which causes pain or a burning feeling when passing water or the need to pass water more often
- **Tender breasts**
- **Stomach problems**, such as stomach ache, bloated feeling, constipation and wind
- **Swelling** (often in the hands or feet)
- **Skin problems** such as acne and rash
- **Muscle spasms**
- **Pain** in the hands, arms, legs or back

Uncommon (affects more than 1 in 1,000 people)

- **Breast problems** such as fuller breasts, discharge from the nipples, including milky fluid
- Change in **sex drive**
- **Muscle pains**
- **Skin problems** including
 - patches of **darkened skin** (which may not disappear)
 - red or itchy skin
- **Tingling or numbness** in the hands or feet
- Changes in **appetite**
- **Hair thinning** (alopecia) or **excessive hair growth**
- **Weight loss** or weight not stable
- **Dry eyes**
- Changes in **vision**
- Feeling **worried**
- Feeling **faint**
- Being **aware of heart beat** (palpitations)

- **Hot flushes**
- **Gynaecological problems**
 - **dryness of the vagina**
 - **stomach** pain, discomfort and swelling with changes in periods (could be signs of a cyst on the ovary)

Rare (affects fewer than **1 in 1,000** people)

- Feeling **giddy** (vertigo)
- Unusually fast **heartbeat**
- **Severe upper stomach** and **back pain** that is often worse after eating (could be signs of inflammation of the pancreas)
- Increased **sweating** (including night sweats)
- **Itchy, red patches** on exposed **skin** (sun sensitivity)

Other side effects (frequency not known)

- Decrease in breast milk
- **Contact lenses** may feel uncomfortable
- High or low **fat (lipid) levels** in the blood
- **Fits** or convulsions
- Red, tender lumps on the skin often on the legs

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: 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. Also tell your doctor, pharmacist or nurse if any existing conditions get worse while you are taking Cilest.

4.3 Bleeding between periods should not last long

A few women have a little unexpected bleeding or spotting while they are taking Cilest, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking Cilest 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 Cilest for a while
- carries on even after you've stopped taking Cilest

5 How to store Cilest

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

Do not store above 25°C. Keep the blister in the outer carton to protect it from light.

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

Do not throw away any medicines down a drain or into a bin. Ask your pharmacist what to do with any medicines you do not want. This will help to protect the environment.

6 Contents of the pack and other information

What Cilest contains

Each pill contains 250 micrograms norgestimate and 35 micrograms ethinylestradiol.

Cilest also contains the inactive ingredients: lactose monohydrate (a type of sugar), microcrystalline cellulose, croscarmellose sodium, magnesium stearate, hypromellose, carnauba wax, polyethylene glycol, polysorbate 80, purified water, titanium dioxide and a dye called FD&C Blue No 2 Aluminium Lake (E132).

What Cilest looks like and contents of the pack

Each box of Cilest contains one or three strips of 21 tablets.

The tablets are blue, round, biconvex coated tablets, imprinted with '0 250' on one side and '35' on the other side

Marketing Authorisation Holder:

Janssen-Cilag Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire HP12 4EG, UK

Manufacturer:

Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium

For information in large print, tape, CD or Braille, telephone 1800 709 122.

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