

# LUCETTE®

## 0.03 mg/3 mg film-coated tablets

Ethinylestradiol and Drospirenone

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

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

### Read all of this leaflet carefully before you start 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 Lucette is and what it is used for
2. What you need to know before you use Lucette
3. How to take Lucette
4. Possible side effects
5. How to store Lucette
6. Contents of the pack and other information

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

- Lucette is a contraceptive pill and is used to prevent pregnancy.
- Each tablet contains a small amount of two different female hormones, namely ethinylestradiol and drospirenone.
- Contraceptive pills that contain two hormones are called "combination" pills.

### 2. WHAT YOU NEED TO KNOW BEFORE YOU USE LUCETTE

#### General notes

Before you start using Lucette you should read the information on blood clots in section 2. It is particularly important to read the symptoms of a blood clot – see Section 2 "Blood clots".

Before you can begin taking Lucette, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure and, depending upon your personal situation, may also carry out some other tests.

In this leaflet, several situations are described where you should stop using Lucette, or where the reliability of Lucette may be decreased. In such situations you should either not have sex or you should take extra non-hormonal contraceptive precautions, e.g. use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because Lucette alters the monthly changes of body temperature and cervical mucus.

#### Lucette, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

#### Do not use Lucette

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

- if you are allergic to ethinylestradiol or drospirenone, or any of the other ingredients of this medicine (listed in section 6.). This may cause itching, rash or swelling;
- if you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs;
- if you know you have a disorder affecting your blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies;
- if you need an operation or if you are off your feet for a long time (see section "Blood clots");
- if you have ever had a heart attack or a stroke;
- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA – temporary stroke symptoms);
- if you have any of the following diseases that may increase your risk of a clot in the arteries:
  - severe diabetes with blood vessel damage
  - very high blood pressure
  - a very high level of fat in the blood (cholesterol or triglycerides)
  - a condition known as hyperhomocysteinaemia.
- if you have (or have ever had) a type of migraine called 'migraine with aura';
- if you have (or have ever had) a liver disease and your liver function is still not normal;
- if your kidneys are not working well (renal failure);
- if you have (or have ever had) a tumour in the liver;
- if you have (or have ever had) or if you are suspected of having breast cancer or cancer of the genital organs;
- if you have any unexplained bleeding from the vagina.
- Lucette contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Lucette.

When should you contact your doctor?

#### Seek urgent medical attention

- if you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke (see 'Blood clots' section below). For a description of the symptoms of these serious side effects please go to "How to recognise a blood clot".

#### Tell your doctor if any of the following conditions apply to you.

In some situations you need to take special care while using Lucette or any other combination pill, and your doctor may need to examine you regularly. If any of the following conditions applies to you, tell your doctor before starting to use Lucette. If the condition develops, or gets worse while you are using Lucette, you should also tell your doctor.

If you have:

- a close relative who has ever had breast cancer.
- a disease of the liver or the gallbladder.
- diabetes.
- depression.
- epilepsy (see "Other medicines and Lucette").
- a disease that first appeared during pregnancy or earlier use of sex hormones (for example, hearing loss, a blood disease called porphyria, yellowing of the skin or eyes (jaundice), itching of the whole body (pruritus), skin rash with blisters during pregnancy (gestational herpes), a nerve disease causing sudden movements of the body (Sydenham's chorea)).
- ever had a discolouration of the skin especially on the face or neck known as "pregnancy patches", (chloasma). If so, avoid direct sunlight or ultraviolet light.
- hereditary angioedema, products containing oestrogens may cause or worsen the symptoms. You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing.
- Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease).
- systemic lupus erythematosus (SLE - a disease affecting your natural defence system).
- haemolytic uraemic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys).
- sickle cell anaemia (an inherited disease of the red blood cells).
- 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 in section 2 "Blood clots").
- 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 Lucette.
- an inflammation in the veins under the skin (superficial thrombophlebitis).
- varicose veins.

### BLOOD CLOTS

Using a combined hormonal contraceptive such as Lucette 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 a 'venous thrombosis', 'venous thromboembolism' or VTE)
- in the arteries (referred to as an 'arterial thrombosis', 'arterial thromboembolism' or ATE).

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, they may be fatal.

It is important to remember that the overall risk of a harmful blood clot due to Lucette 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"> <li>• swelling of one leg or along a vein in the leg or foot especially when accompanied by:               <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 e.g. turning pale, red or blue.</li> </ul> </li> </ul>	Deep vein thrombosis
<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
Symptoms most commonly occur in one eye: <ul style="list-style-type: none"> <li>• immediate loss of vision or</li> <li>• painless blurring of vision which can progress to loss of vision</li> </ul>	Retinal vein thrombosis (blood clot in the eye)
<ul style="list-style-type: none"> <li>• chest pain, discomfort, pressure, 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 radiating 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 heart beats.</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
Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.	
<ul style="list-style-type: none"> <li>• swelling and slight blue discolouration of an extremity;</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 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 Lucette your risk of a blood clot returns to normal within a few weeks.

#### What is the risk of developing a blood clot?

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

- The overall risk of a blood clot in the leg or lung (DVT or PE) with Lucette is small.
- Out of 10,000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains levonorgestrel, norethisterone, or norgestimate about 5-7 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains drospirenone, such as Lucette between about 9 and 12 women 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 <b>not using</b> a combined hormonal pill/patch/ring and are not pregnant	About 2 out of 10,000 women
Women using a combined hormonal contraceptive pill containing <b>levonorgestrel, norethisterone or norgestimate</b>	About 5-7 out of 10,000 women
Women using Lucette	About 9-12 out of 10,000 women

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

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

- if you are very overweight (body mass index or BMI over 30kg/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 (e.g. below the age of about 50). In this case you could have a hereditary blood clotting disorder;
- if you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of Lucette may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Lucette ask your doctor when you can start using it again;
- as you get older (particularly above about 35 years);
- if you gave birth less than a few weeks ago.

The risk of developing a blood clot increases the more conditions you have.

Air travel (>4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.

It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that Lucette needs to be stopped.

If any of the above conditions change while you are using Lucette, for example a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

### BLOOD CLOTS IN AN ARTERY

#### What can happen if a blood clot forms in an artery?

Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

#### Factors that increase your risk of a blood clot in an artery

It is important to note that the risk of a heart attack or stroke from using Lucette is very small but can increase:

- with increasing age (beyond about 35 years);
- **if you smoke.** When using a combined hormonal contraceptive like Lucette you are advised to stop smoking. If you are unable to stop smoking and are older than 35 your doctor may advise you to use a different type of contraceptive;
- if you are overweight;
- if you have high blood pressure;
- if a member of your immediate family has had a heart attack or stroke at a young age (less than about 50). In this case you could also have a higher risk of having a heart attack or stroke;
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides);
- if you get migraines, especially migraines with aura;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation);
- if you have diabetes.

If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot may be increased even more.

If any of the above conditions change while you are using Lucette, for example you start smoking, a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

#### Lucette and cancer

Breast cancer has been observed slightly more often in women using combination pills, but it is not known whether this is caused by the treatment. For example it may be that more tumours are detected in women on combination pills because they are examined by their doctor more often. The risk of breast tumours becomes gradually less after stopping the combination hormonal contraceptives. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in pill users. Contact your doctor if you have unusually severe abdominal pain.

#### Bleeding between periods

During the first few months that you are taking Lucette, you may have unexpected bleeding (bleeding outside the seven pill-free days). If this bleeding occurs for more than a few months, or if it begins after some months, contact your doctor as they must find out if anything is wrong.

#### What to do if no bleeding occurs during the seven pill-free days

If you have taken all the tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant.

If the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Only start the next strip if you are sure that you are not pregnant.

#### Other medicines and Lucette

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you are taking this medicine. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long.

Some medicines can make Lucette less effective in preventing pregnancy, or can cause unexpected bleeding. These include medicines used for the treatment of

- epilepsy (e.g. barbiturates, carbamazepine, phenytoin, primidon, oxcarbazepine);
- tuberculosis (e.g. rifampicin);
- HIV infections (e.g. ritonavir, nevirapine) or other infections (antibiotics such as griseofulvin, penicillin, tetracycline);
- high blood pressure in the blood vessels in the lungs (bosentan);
- the herbal remedy St. John's wort.

Lucette may influence the effect of other medicines, e.g.

- medicines containing ciclosporin
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures).

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

#### Taking Lucette with food and drink

Lucette may be taken with or without food, if necessary with a small amount of water.

#### Laboratory tests

If you need a blood test, tell your doctor or the laboratory staff that you are taking the pill, because hormonal contraceptives can affect the results of some tests.

