

## Package leaflet: Information for the patient

### **Mylite 100 micrograms / 20 micrograms coated tablets** (levonorgestrel and ethinylestradiol)

**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, even if their symptoms are the same as yours.
- 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.

#### **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”).

#### **What is in this leaflet**

1. What Mylite is and what it is used for
2. What you need to know before you take Mylite
3. How to take Mylite
4. Possible side effects
5. How to store Mylite
6. Contents of the pack and other information

#### **1. What Mylite is and what it is used for**

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

#### **2. What you need to know before you take Mylite**

##### **General notes**

Before you start using Mylite 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 Mylite, your doctor will ask you some questions about your personal health 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 Mylite, or where the reliability of Mylite may be decreased. In such situations you should either not have intercourse 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 Mylite alters the monthly changes of the body temperature and the cervical mucus.

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

### **When you should not use Mylite**

You should not use Mylite 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.

### **Do not take Mylite**

- 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) severe liver disease and your liver function is still not normal.
- if you have (or have ever had) a tumour in the liver
- if you have (or have ever had) or suspect you have breast cancer or cancer of the genital organs
- if you have any unexplained bleeding from the vagina
- if you have stopped menstruating, possibly due to exercise or diet
- if you have an allergy (hypersensitivity) to ethinylestradiol, levonorgestrel, or to any of the other ingredients of this medicine (listed in section 6). This may cause itching, rash or swelling.

Do not use Mylite if you have hepatitis C and are taking medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir and sofosbuvir/velpatasvir/voxilaprevir (see also in section “Other medicines and Mylite”).

## **Additional information on special populations**

### *Use in children*

Mylite is not intended for use in females whose periods have not yet started.

### *Use in older women*

Mylite is not intended for use after the menopause.

### *Women with liver impairment*

Do not take Mylite if you suffer from liver disease. See also sections ‘When you should not use Mylite’ and ‘Warnings and precautions’.

### *Women with kidney impairment*

Ask your doctor. Available data do not suggest a need to change the use of Mylite.

## **Warnings and precautions**

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.**

Talk to your doctor before taking Mylite. In some situations you need to take special care while using Mylite or any other combination pill, and it may be necessary that you are regularly checked by your doctor. If the condition develops or gets worse while you are using Mylite, you should also tell your doctor.

- If a close relative has had breast cancer.
- If you have liver or gallbladder disease.
- If you have diabetes.
- If you have depression.
- If you have Crohn’s disease or ulcerative colitis (chronic inflammatory bowel disease).
- If you have haemolytic uraemic syndrome (HUS- a disorder of blood clotting causing failure of the kidneys)
- If you have systemic lupus erythematosus (SLE-a disease affecting your natural defense system).
- if you have sickle cell anaemia (an inherited disease of the red blood cells);

- 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 in section 2 ‘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 Mylite;
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- if you have varicose veins;
- if you have epilepsy (see “Other medicines and Mylite”);
- if you have a disease that first appeared during pregnancy or with earlier use of sex hormones (for example, hearing loss, a blood disease called porphyria, skin rash with blisters during pregnancy (gestational herpes), or a nerve disease causing sudden movements of the body (Sydenham’s chorea);
- if you have ever had golden brown pigment patches (chloasma), so called “pregnancy patches”, especially on the face. If this is the case, avoid direct exposure to sunlight or ultraviolet light;
- if you have hereditary angioedema (rapid swelling of the skin, mucosal tissues, internal organs or brain); products containing oestrogens may cause or worsen the symptoms. **If you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Products containing oestrogens may cause or worsen the symptoms of hereditary and acquired angioedema.**

## BLOOD CLOTS

Using a combined hormonal contraceptive such as Mylite 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 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 Mylite 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> </ul> </li> </ul>	Deep vein thrombosis

<ul style="list-style-type: none"> <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>	
<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
<p>Symptoms most commonly occur in one eye:</p> <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 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> <p>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.</p>	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
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## 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 Mylite 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 Mylite 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 such as Mylite, 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 and are not pregnant	About 2 out of 10,000 women

Women using a combined hormonal contraceptive pill containing <b>levonorgestrel</b>	About 5-7 out of 10,000 women
Women using Mylite	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 Mylite 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 Mylite may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Mylite, 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 Mylite needs to be stopped.

If any of the above conditions change while you are using Mylite, 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 Mylite is very small but can increase:

- with increasing age (beyond about 35 years);

- **if you smoke.** When using a combined hormonal contraceptive like Mylite 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 Mylite, 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.

### **Mylite and cancer**

Cervical cancer in long-term users has been reported, but it is not clear if it is contributed by sexual behavior or other factors such as human papilloma virus (HPV).

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 combined pills because they are examined by their doctor more often. The occurrence 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 unusual severe abdominal pain.

### **Bleeding between periods**

During the first few months that you are taking Mylite, you may have unexpected bleeding (bleeding outside the gap week). If this bleeding occurs for more than 3 months, or if it begins after some months, your doctor must investigate the cause.

### **What you must do if no bleeding occurs in the gap week**

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 as pregnancy must be ruled out before the pill is continued. Do not start the next strip until you are sure that you are not pregnant.

### **Psychiatric disorders**

Some women using hormonal contraceptives including Mylite 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 medicines and Mylite**

Tell the doctor, 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 Mylite. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long.

Do not use Mylite if you have Hepatitis C and are taking medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir and sofosbuvir/velpatasvir/voxilaprevir, as these products 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.

Mylite can be restarted approximately 2 weeks after completion of this treatment. See section “Do not take Mylite”.

Some medicines can have an influence on the blood levels of Mylite and can make it less effective in preventing pregnancy, or can cause unexpected bleeding. They include

- medicines used for the treatment of
  - gastrointestinal motility (e.g. metoclopramide)
  - epilepsy (e.g, primidone, phenytoin, barbiturates, carbamazepine, oxcarbamazepine, topiramate, felbamate)
  - tuberculosis (e.g. rifampicin)
  - arthritis, arthrosis (etoricoxib)
  - high blood pressure in the blood vessels in the lungs (bosentan)
  - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efavirenz)
  - fungal infections (griseofulvin)
- the herbal remedy St. John’s wort.

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

- medicines containing cyclosporin
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures).
- Troleandomycin (an antibiotic) may increase the risk of cholestasis (a situation where bile flow from the liver is inhibited) when given together with a combination pill.
- theophylline (used to treat breathing problems)
- tizanidine (used to treat muscle pain and or muscle cramps)

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

**Effect on 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.

**Pregnancy**

If you are pregnant, you must not take Mylite. If you become pregnant while taking Mylite you must stop immediately and contact your doctor.

If you want to become pregnant, you can stop taking Mylite at any time.

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

**Breast-feeding**

Taking of Mylite is generally not advisable when a woman is breast feeding. If you want to take the pill while you are breast-feeding you should contact your doctor.

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

**Driving and using machines**

There is no information suggesting that use of Mylite affects driving or use of machines.

**Mylite contains lactose, sucrose and sodium**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

**3. How to take Mylite**

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

Take one tablet of Mylite every day for 21 days, if necessary with a small amount of water. You may take the tablets with or without food, but you should take the tablets every day around the same time.

The strip contains 21 tablets. Next to each tablet is printed the day of the week that it should be taken. If, for example you start on a Wednesday, take a tablet with "WED" next to it. Follow the direction of the arrow on the strip until all 21 tablets have been taken.

Then take no tablets for 7 days. In the course of these 7 tablet-free days (otherwise called a stop or gap week) bleeding should begin. This so-called "withdrawal bleeding" usually starts on the 2<sup>nd</sup> or 3<sup>rd</sup> day of the gap week.

On the 8th day after the last Mylite (that is, after the 7-day gap week), start the following strip, even if the bleeding has not stopped. This means that you should start the following strip on the same day of the week and that the withdrawal bleed should occur on the same days each month.

If you use Mylite in this manner, you are also protected against pregnancy during the 7 days that you are not taking a tablet.

### **Starting the first pack of Mylite**

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

Begin with Mylite on the first day of the cycle (that is the first day of your menstruation). If you start Mylite on the first day of your menstruation you are immediately protected against pregnancy. You may also begin on day 2-5 of your cycle, but then you must use extra protective measures (for example, a condom) for the first 7 days.

- **Changing from another combination hormonal contraceptive, or combination contraceptive, vaginal ring or patch.**

You can start Mylite preferably on the day after the last active tablet (the last tablet containing the active substance) of your previous pill (or after removal of the ring or patch), or at the latest, on the day after the tablet-free (ring-free, patch-free) days of your previous pill finish (or after the last inactive tablet of your previous pill).

- **Changing from a progestogen-only-method (oral pill, injection, implant or an intrauterine system IUS).**

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

- **After first trimester miscarriage.**

Follow the advice of your doctor.

- **After having a baby or second trimester termination.**

You can start Mylite between 21 and 28 days after delivery or second trimester abortion. If you start later than day 28, you must use an additional barrier method (for example, a condom) during the first seven days of Mylite use.

If, after having a baby, you have had intercourse before starting Mylite (again), you must first be sure that you are not pregnant or you must wait until the next menstrual bleed.

Ask your doctor what to do if you are not sure when to start.

- **If you are breast-feeding and want to start Mylite after having a baby.**

Read the section on “Breast-feeding”.

### **If you take more Mylite than you should**

There are no reports of serious harmful results from taking too many levonorgestrel/ethinylestradiol.

If you take several tablets at once then you may have symptoms of nausea or vomiting. Young girls may have bleeding from the vagina.

If you have taken too many Mylite, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

### **If you forget to take Mylite**

- If you are **less than 12 hours late** in taking your pill, the protection from pregnancy is not reduced. Take the tablet as soon as you remember, and further pills again at the usual time.
- If you are **more than 12 hours late** taking a tablet, the protection from pregnancy may be reduced. The greater the number of tablets that you have forgotten, the greater is the risk that the protection from pregnancy is reduced.

The risk of incomplete protection against pregnancy is greatest if you forget a tablet at the beginning or the end of the strip. Therefore, you should adhere to the following rules (see the diagram):

- Tablet taking must never be discontinued for longer than 7 days.
- Effectiveness of Mylite depends on 7 days uninterrupted tablet-taking

- **More than one tablet forgotten in this strip**

Contact your doctor.

- **One tablet forgotten in week 1**

Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Take the tablets again at the usual time and use **extra precautions** for the next 7 days, for example, a condom. If you have had intercourse in the week before the oversight, you must realize that there is a risk of pregnancy. The more tablets have been missed and the closer they are to the regular tablet-free break, the higher the risk of pregnancy. In that case, contact your doctor.

- **One tablet forgotten in week 2**

Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. The protection against pregnancy is not reduced, and you do not need to take extra precautions. If you have not taken the tablets correctly or have missed more than one tablet, you should use extra contraceptive precautions for the next 7 days.

- **One tablet forgotten in week 3**

The risk of pregnancy increases the nearer you are to the tablet-free break of 7 days. However, pregnancy can still be prevented by adjusting the dosage.

If you use the following advice, there is no need to use extra contraceptive precautions, provided that all the tablets have been taken correctly in the 7 days before the first missed tablet. If this is not the case, you should follow the first of these two options and use extra contraceptive precautions for the next 7 days as well:

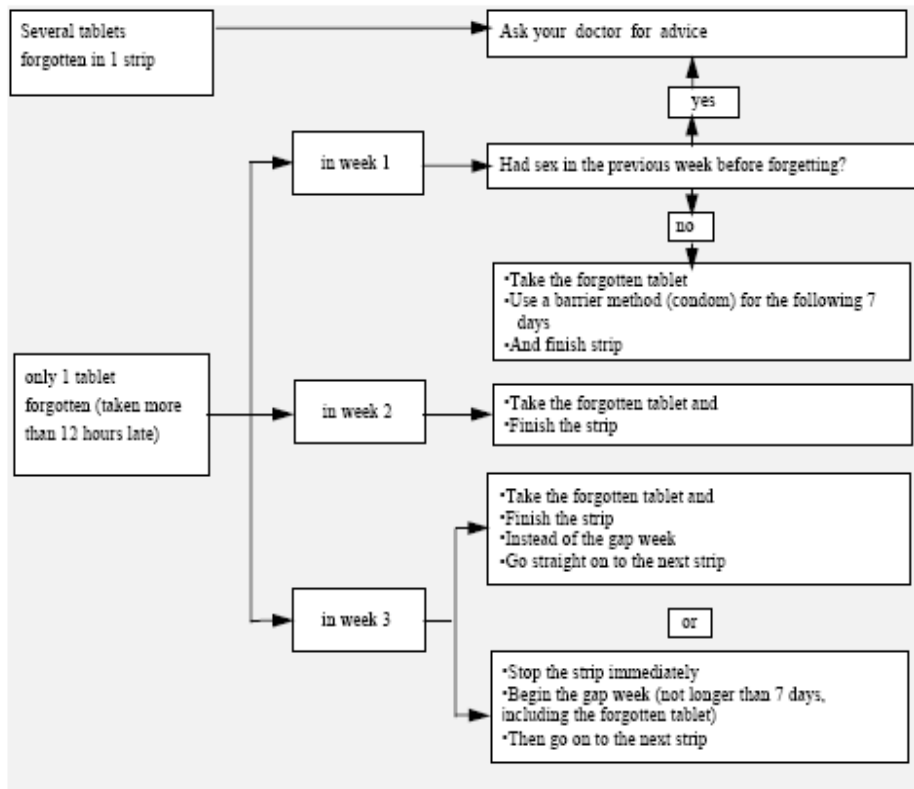
1. Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Take the tablets again at the usual time. Instead of the tablet-free period go straight on to the next strip.

Most likely, you will have a period (withdrawal bleed) at the end of the second strip but you may also have spotting or breakthrough bleeding during the second strip.

Or

2. You can also stop the strip and go directly to the tablet-free period of 7 days (**record the day on which you forgot your tablet**). If you want to start a new strip on your fixed start day, make the tablet-free period less than 7 days.

If you have forgotten any of the tablets in a strip, and you do not have bleeding in the first tablet-free period, this may mean that you are pregnant. You must contact your doctor before you go on to the next strip.



### What must you do in the case of vomiting or severe diarrhoea

If you vomit within 3-4 hours of taking a tablet or you have severe diarrhoea, there is a risk that the active substance in the pill are not fully adsorbed into your body. The situation is similar to if you forget a tablet. After vomiting or diarrhoea, you must take another tablet from a reserve strip as soon as possible. If possible take it within 12 hours of when you normally take your pill. If this is not possible or 12 hours have passed, you should follow the advice given under ‘if you forget to take Mylite.

### Delay of menstrual period: what must you need to know

Even if not recommended, delay of your menstrual period (withdrawal bleed) is possible by going straight on to a new strip of Mylite instead of the tablet-free period and finishing it. You may experience light or menstruation-like bleeding while using this second strip. After the second strip is finished, take the usual tablet-free period of 7 days break.

### You should ask your doctor for advice before deciding to delay your period

### Change of the first day of your menstrual period: what you need to know

If you take the tablets according to the instructions, then your period will begin in the tablet-free week. If you have to change this day, do this by making the tablet-free period shorter (*but never increase them-7 is the maximum!*) For example, if your tablet-free period begins on a Friday, and you want to change this to a Tuesday (3 days earlier) you must start a new strip 3 days earlier than usual. If you make the tablet-free period very short (for example, 3 days or less) then it may be that you do not have any bleeding during this tablet-free period. You may then experience light or menstruation like bleeding spotting.

**If you are not sure how to proceed, contact your doctor for advice.**

#### **If you want to stop taking Mylite**

You can stop taking Mylite whenever you want. If you do not want to become pregnant, ask your doctor for advice about other reliable methods of birth control. If you want to become pregnant, stop taking Mylite and wait for a period before trying to become pregnant. You will be able to calculate the expected delivery date more easily.

*If you have any further questions on the use of this product, ask your doctor or pharmacist.*

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be due to Mylite, please talk to your doctor.

An increased risk of blood clots in the veins (venous thromboembolism (VTE)) or blood clots in the arteries (arterial thromboembolism (ATE)) is present for all women using combined hormonal contraceptives. For more detailed information on the different risks from taking combined hormonal contraceptives please see section 2 “What you need to know before you take Mylite”.

The following is a list of the side effects that have been linked with the use of Mylite:

**If any of the following side effects happen, you may need urgent medical attention. Stop taking Mylite and contact a doctor or go to the nearest hospital immediately.**

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

- A serious allergic reaction which includes signs such as rash, itching or hives on the skin, swelling of the face, lips, tongue or throat which may cause difficulty in breathing and swallowing.
- Harmful blood clots in a vein or artery for example:
  - o in a leg or foot (i.e. deep vein thrombosis (DVT))
  - o in a lung (i.e. pulmonary embolism (PE))
  - o heart attack
  - o stroke
  - o mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA)
  - o blood clots in the liver, stomach/intestine, kidneys or eye.

The chance of having a blood clot may be higher if you have any other conditions that increase this risk (See section 2 for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot).

The following serious adverse events have been reported slightly more often in women using contraceptive pills but it is not known whether this is caused by the treatment (see section 2 “What you need to know before you take Mylite”):

- raised blood pressure
- liver tumours or breast cancer

In women with hereditary exogenous angioedema (rapid swelling of the skin, mucosal tissues, internal organs or brain), the oestrogens in contraceptive pills may induce or exacerbate symptoms of angioedema (see Section 2 “Warnings and precautions”).

Contact a doctor immediately if you experience any of the following symptoms of angioedema: swollen face, tongue, and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also section “Warnings and precautions”).

### **Other possible side effects**

Common side effects (may affect up to 1 in 10 people):

- Nausea
- Abdominal pain
- Weight increased
- Headache
- Depressed mood
- Mood altered
- Breast tenderness
- Breast pain

Uncommon side effects (may affect up to 1 in 100 people):

- Vomiting
- Diarrhoea
- Fluid retention
- Migraine (throbbing headache, usually affecting one side of the head)
- Decreased interest in sex
- Breast enlargement
- Rash
- Urticaria (pinkish, itchy swellings on the skin)

Rare side effects (may affect up to 1 in 1000 people):

- Contact lens intolerance
- Weight decreased
- Increased interest in sex
- Breast discharge
- Vaginal discharge
- Painful bluereddish bumps in the skin
- Rash with abnormal red spots

**The following conditions have also been associated with combination oral contraception:**

- Crohn's disease, ulcerative colitis (inflammation of the colon or other parts of the intestine with signs such as bloody diarrhoea, pain when passing stools, pain in the abdomen)
- Porphyria (metabolism disorder which causes abdominal pains and mental disorders)
- Systemic lupus erythematosus (where the body attacks and injures its own organs and tissues)
- Herpes (skin rash with vesicles during pregnancy) in late pregnancy
- Sydenham's chorea (rapid involuntary jerking or twitching movements)
- Haemolytic uraemic syndrome (a condition which occurs after diarrhoea caused by *E.coli*)
- Liver problems shown by jaundice.
- Increase risk of inflammation of the pancreas (pancreatitis) in women with hypertriglyceridemia
- Gallstone formation
- Cholestatic jaundice (yellowing of the skin or whites of the eyes due to obstruction in the bile duct)
- Otosclerosis (related hearing loss)
- Changes in glucose tolerance or effect on peripheral insulin resistance
- Chloasma (golden brown pigment patches, so called "pregnancy patches", especially on the face)

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects, you can help provide more information on the safety of this medicine.

### **5. How to store Mylite**

This medicinal product does not require any special temperature storage conditions.

Keep out of sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton.

The expiry date refers to the last day of that month.

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

### **6. Contents of the pack and other information**

#### **What Mylite contains**

The active substances are levonorgestrel and ethinylestradiol.

Each tablet contains 100 micrograms of levonorgestrel and 20 micrograms of ethinylestradiol.

The other ingredients are:

Tablet core: lactose monohydrate (see section 2 ‘Mylite contains lactose, and sucrose and sodium’), microcrystalline cellulose, croscarmellose sodium (see section 2 ‘Mylite contains lactose, and sucrose and sodium’), povidone, magnesium Stearate VG.

Coating: povidone, talc, glycerol, isopropyl alcohol, sucrose (see section 2 ‘Mylite contains lactose, and sucrose and sodium’), calcium carbonate, macrogol 6000, titanium dioxide (E171), iron oxide (red) (E172), iron oxide (yellow) (E172), carnauba wax

**What Mylite look like and contents of the pack**

Mylite are pink, round (5.60 mm diameter), coated biconvex tablets, plain on both sides.

Each blister pack contains 21 tablets.

Mylite are sold in cartons/pouch of 1, 3, 6 or 13 blisters packs. Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

**Manufacturer**

Mylan Hungary Kft.  
H-2900 Komárom, Mylan utca 1., Hungary

Generics [UK] Limited  
Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

**This medicinal product is authorised in the Member States of the EEA under the following names:**

NL: Ethinylestradiol/Levonorgestrel Mylan 0,02/0,10 mg omhulde tabletten

IE: Mylite 100 micrograms / 20 micrograms coated tablets

This leaflet was last updated in 07/2020.