**Package leaflet: Information for the user**

**Microlite 100 microgram/20 microgram coated tablets**
levonorgestrel/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. 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 effets, 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 Microlite is and what it is used for
2. What you need to know before you take Microlite
3. How to take Microlite
4. Possible side effects
5. How to store Microlite
6. Contents of the pack and other information

## 1. What Microlite is and what it is used for
- Microlite is a contraceptive pill and is 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. Microlite is called a ‘low-dose’ contraceptive pill because it contains only a small amount of hormones.

## 2. What you need to know before you take Microlite

**General notes**

Before you start using Microlite 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 Microlite, 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 Microlite, or where the reliability of Microlite 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 Microlite alters the monthly changes of body temperature and of cervical mucus.

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

**When you should not use Microlite**

You should not use Microlite 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 use Microlite**:

- 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 Microlite if you have hepatitis C and are taking medicines containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see also in section "Other medicines and Microlite").

If any of these conditions start while you are using Microlite, stop taking the pills immediately and talk to your doctor.

**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 Microlite. In some situations you need to take special care while using Microlite 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 Microlite, 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 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 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 Microlite;
- 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 Microlite");
- 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 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. Medicines containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema.

**BLOOD CLOTS**

Using a combined hormonal contraceptive such as Microlite 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 Microlite 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? |
|---|---|
| • swelling of one leg or along a vein in the leg or foot especially when accompanied by:<br>  • pain or tenderness in the leg which may be felt only when standing or walking<br>  • increased warmth in the affected leg<br>  • change in colour of the skin on the leg e.g. turning pale, red or blue. | Deep vein thrombosis |
| • sudden unexplained breathlessness or rapid breathing;<br>• sudden cough without an obvious cause, which may bring up blood;<br>• sharp chest pain which may increase with deep breathing;<br>• severe light headedness or dizziness;<br>• rapid or irregular heartbeat;<br>• severe pain in your stomach.<br>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'). | Pulmonary embolism |
| Symptoms most commonly occur in one eye:<br>• immediate loss of vision or<br>• painless blurring of vision which can progress to loss of vision. | Retinal vein thrombosis (blood clot in the eye) |
| • chest pain, discomfort, pressure, heaviness;<br>• sensation of squeezing or fullness in the chest, arm or below the breastbone;<br>• fullness, indigestion or choking feeling;<br>• upper body discomfort radiating to the back, jaw, throat, arm and stomach;<br>• sweating, nausea, vomiting or dizziness;<br>• extreme weakness, anxiety, or shortness of breath;<br>• rapid or irregular heartbeats. | Heart attack |
| • sudden weakness or numbness of the face, arm or leg, especially on one side of the body; | Stroke |

| | |
|---|---|
| • sudden confusion, trouble speaking or understanding;<br>• sudden trouble seeing in one or both eyes;<br>• sudden trouble walking, dizziness, loss of balance or coordination;<br>• sudden, severe or prolonged headache with no known cause;<br>• loss of consciousness or fainting with or without seizure.<br><br>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.. | |
| • swelling and slight blue discolouration of an extremity;<br>• severe pain in your stomach (acute abdomen). | 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 medicine or a different medicine) 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 Microlite 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 Microlite 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 Microlite, 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 pill and are not pregnant | About 2 out of 10,000 women |
| Women using a combined hormonal contraceptive pill containing **levonorgestrel** | About 5-7 out of 10,000 women |
| Women using Microlite | 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 Microlite 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$^2$);
- 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 Microlite may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Microlite, 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 Microlite needs to be stopped.

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

- with increasing age (beyond about 35 years);
- **if you smoke.** When using a combined hormonal contraceptive like Microlite 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 Microlite, 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.

**Microlite and cancer**

- Cervical cancer in long-term users has been reported, but it is not clear if it is contributed by sexual behaviour 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. The occurrence of breast tumours reduces after stopping the tablets. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.
- Benign liver tumours (non-cancerous) are rare, and malignant liver tumours (cancerous) are even more rarely reported in combination pill users. Contact your doctor if you have unusually severe stomach pain.

**Psychiatric disorders**

Some women using hormonal contraceptives including Microlite 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.

**Bleeding between periods**

During the first few months when you are taking Microlite, you may have unexpected bleeding (bleeding outside the pill-free days). If this bleeding occurs for more than three months, or if it begins after some months, your doctor must find out what is wrong.

**What to do if no bleeding occurs during the tablet-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.

However 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. Only start the next strip if you are sure that you are not pregnant.

**Other medicines and Microlite**

| |
|---|
| Tell your 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 use Microlite. They can tell you if you need to use additional contraceptive precautions (for example, condoms) and if so, for how long. |

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

These include:

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

The antibiotic troleandomycin may increase the risk of bile retention if taken together with the pill.

Microlite may influence the effect of other medicines, e.g.
- medicines containing cyclosporine (used to suppress the body's immune response)
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures)
- theophylline (used to treat breathing problems)
- tizanidine (used to treat muscle pain and/or muscle cramps).

Do not use Microlite if you have hepatitis C and are taking medicines containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir, as these medicines 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 medicines.

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

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

**Microlite with food and drink**

Microlite may be taken with or without food, if necessary with a small amount of water. Microlite should not be taken with grapefruit juice.

**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**
Do not take Microlite if you are pregnant. If you become pregnant while taking Microlite stop taking Microlite immediately and contact your doctor. If you want to become pregnant, you can stop taking Microlite at any time (see also “If you stop taking Microlite”).

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

**Breast-feeding**

Taking Microlite is not advisable during breast-feeding unless advised to by your doctor. 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 Microlite affects driving or using machines.

**Microlite contains lactose and sucrose**
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## 3. How to take Microlite

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

Each blister strip contains 21 tablets. Each tablet is marked with the weekday when the tablet should be taken. For example, if you start to take the tablets on a Tuesday, press the tablet through the aluminium foil, at a blister marked "TUE". Take the tablets every day in the order shown by the arrows.

Take one tablet of Microlite 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.

Once you have finished all 21 tablets, you will not take any tablets during the next 7 days. Your period (withdrawal bleed) will start during these 7 days, usually 2–3 days after taking the last Microlite tablet.

Start the next blister pack on the 8$^{th}$ day even if your period continues. This way you will always start a new pack on the same day of the week, and the withdrawal bleed will occur roughly at the same time each month.

**When can you start with the first strip?**

*If you have not used a contraceptive with hormones in the previous month*
Begin taking Microlite on the first day of the cycle (that is, the first day of your period). If you start Microlite on this day you are immediately protected against pregnancy. You may also begin on day 2-5 of your cycle, but you must use extra protective measures (for example, a condom) for the first 7 days.

*Changing from another combination hormonal contraceptive, or vaginal ring or patch*
Start taking Microlite on the day after the last active tablet of your previous pill (or after removal of the ring or patch) or, at the latest, on the day following the usual tablet-free (ring-free, patch-free) break or the last placebo tablet of the previous hormonal contraceptive.

*Changing from a progestogen-only-method (oral pill, injection, implant or an intrauterine system/device IUS/D).*
You may change to Microlite tablets on any day from a progestogen-only pill (from an implant or an IUS/D 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 termination*
Follow the advice of your doctor.

*After having a baby or second trimester termination*
Start Microlite 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 7 days of Microlite use.

If, after having a baby, you have had sex before starting Microlite (again), you must first be sure that you are not pregnant or you must wait until your next period before taking Microlite.

*If you are breast-feeding and want to start Microlite (again) after having a baby*
Read the section on “Breast-feeding”.

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

**Additional information on special populations**

*Use in children*

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

*Use in older women*

Microlite is not intended for use after the menopause.

*Use in patients with liver impairment*

Do not take Microlite if you suffer from liver disease. See also sections 'When you should not use Microlite' and 'Warnings and precautions'.

*Use in patients with kidney impairment*

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

**If you take more Microlite than you should**

There are no reports of serious harmful results from taking too many Microlite tablets.

If you take several tablets at once then you may feel sick or vomit or bleed from the vagina. Even girls who have not yet started to menstruate but have accidentally taken this medicine may experience such bleeding.

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

**If you forget to take Microlite**

If you are **less than 12 hours** late taking a tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and then take the following tablets at the usual time.

If you are **more than 12 hours** late taking a tablet, the protection against pregnancy may be reduced. The greater the number of tablets that you have forgotten, the greater is the risk of becoming pregnant.

Therefore, you should keep to the following rules:

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

**If you are more than 12 hours late during days 1-7** (see also the diagram):
Take the last missed tablet as soon as you remember, even if this means taking two tablets at the same time. Then continue to take the next tablets at the usual time. In addition, a barrier method such as a condom should be used for the next 7 days. If you have had sex in the 7 days before missing the tablet, the possibility of a pregnancy must be considered. The more tablets have been missed and the closer they are to the regular tablet-free break, the higher the risk of pregnancy. See your doctor if this has happened to you.

**If you are more than 12 hours late during days 8-14** (see also the diagram):

Take the last missed tablet as soon as you remember, even if this means taking two tablets at the same time. Then continue to take the next tablets at the usual time. Provided you have taken the tablets correctly in the 7 days preceding the first missed tablet, there is no need to use extra contraceptive 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.

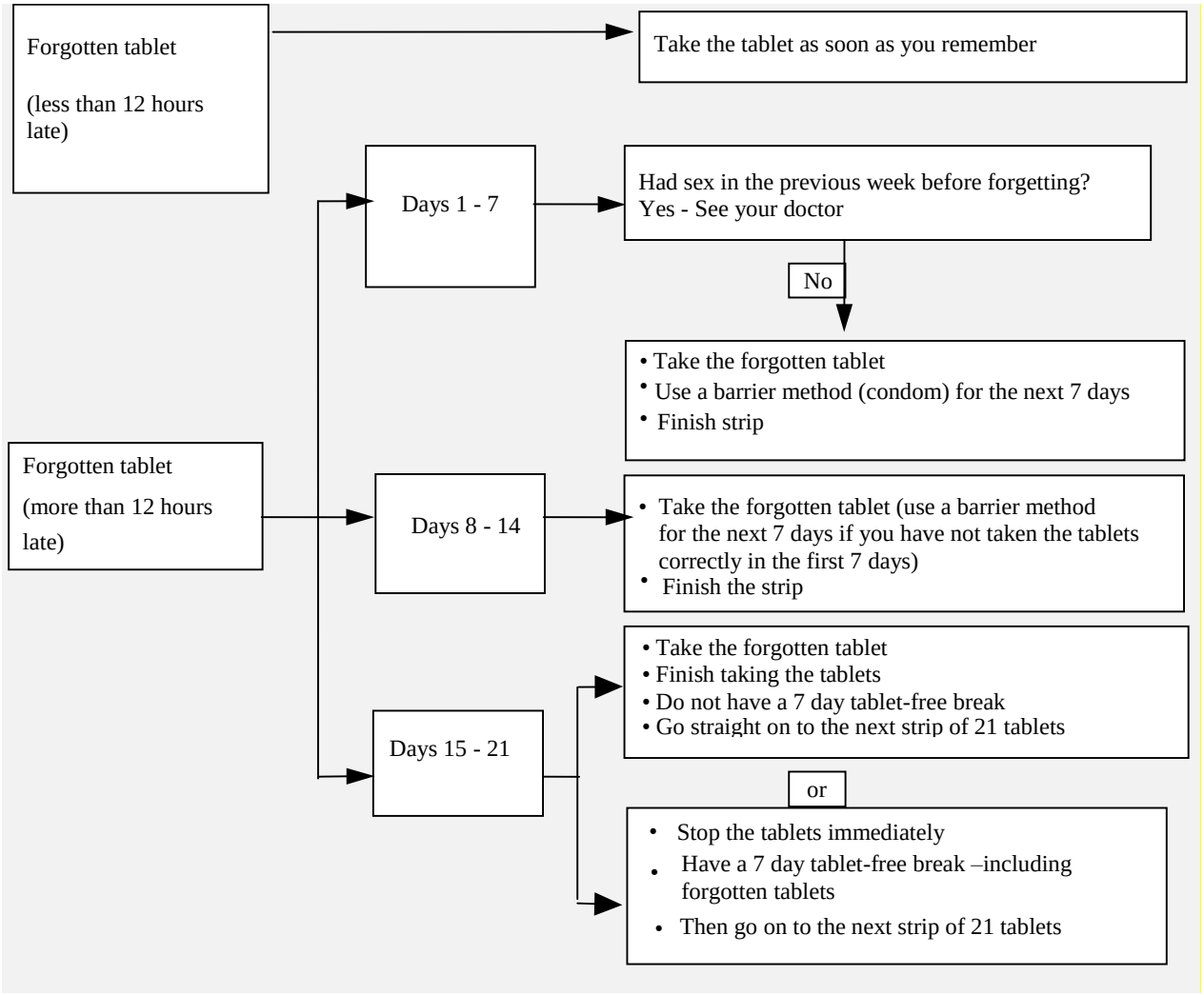
**If you are more than 12 hours late during days 15-21** (see also the diagram):
The risk of pregnancy increases the nearer you are to the tablet-free break of 7 days. However, pregnancy can still be prevented by adjusting the dosage.
If you use the following advice, there is no need to use extra contraceptive 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 taking two tablets at the same time. Then take the rest of the tablets at the usual time. Instead of having a 7 day tablet – free break, continue immediately with the next pack of 21 tablets. There will probably be no withdrawal bleed until the end of the second pack, but you may experience spotting or breakthrough bleeding on tablet-taking days.

or

2. You can stop taking the tablets from the current pack and have a tablet-free break of 7 days, including the days you missed tablets, and then continue with the next pack.

If you miss several tablets and have no withdrawal bleed during the first normal tablet-free break, the possibility of a pregnancy must be considered.




**What to do in the case of vomiting or severe diarrhoea**

If you vomit within 3-4 hours of taking a tablet or have severe diarrhoea, there is a risk that the active substances in the pill will not be fully taken up by your body. The situation is almost the same as forgetting a tablet. After vomiting or diarrhoea, take another tablet from another pack 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, follow the advice given under "If you forget to take Microlite".

**Delaying your period: what you need to know**

Although it is not recommended, you can delay your period by going straight to a new pack of Microlite and finishing it. You may experience spotting (droplets or flecks of blood) or breakthrough bleeding while using this second pack. When the second pack is finished, you must have a 7-day tablet-free break.

***It is advisable to consult your doctor before deciding to delay your menstrual period.***

**Changing of the first day of your menstrual period: what you need to know**

If you want to change the starting day or have your period on another day of the week, you can shorten your next tablet-free break by as many days as you like. The shorter the break, the higher the risk that

there will be no withdrawal bleed and that you will experience breakthrough bleeding and spotting during the second pack. Never lengthen your tablet-free break.

**If you stop taking Microlite**

You can stop taking Microlite 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 Microlite and wait for a menstrual 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 medicine, 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 Microlite, 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 Microlite”.

**Serious side effects**

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”).

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

**Common side effects** (may affect up to 1 in 10 people):
- mood swings, depression
- headache
- nausea, abdominal pain
- breast pain or tenderness
- weight increase

**Uncommon side effects** (may affect up to 1 in 100 people):
- decreased interest in sex
- migraine
- vomiting, diarrhoea
- skin rash
- itching or raised bumps on the skin
- swollen breasts
- fluid retention

**Rare side effects (**may affect up to 1 in 1000 people):
- contact lens intolerance
- allergic reactions
- increased interest in sex
- breast or vaginal discharge
- skin redness or blotchiness

- weight decrease
- harmful blood clots in a vein or artery for example:
  - in a leg or foot (i.e. DVT)
  - in a lung (i.e. PE)
  - heart attack
  - stroke
  - mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA)
  - blood clots in the liver, stomach/intestine, kidneys or eye.

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

- raised blood pressure
- liver tumours or breast cancer

**The following conditions have also been associated with combination oral contraception:**
• women with hypertriglyceridemia (increased blood fats resulting in an increased risk of pancreatitis when using combined oral contraceptives)

• high blood pressure

• occurrence or worsening of conditions for which a link to combined oral contraceptives is not definite: jaundice and/or itching related to cholestasis (blocked bile flow); gallstone formation; a metabolic condition called porphyria; systemic lupus erythematosus (a chronic autoimmune disease); hemolytic uremic syndrome (a blood clotting disease); a neurological condition called Sydenham's chorea; herpes gestationis (a type of skin condition that occurs during pregnancy); otosclerosis-related hearing loss

• disturbed liver function

• changes in glucose tolerance or effect on peripheral insulin resistance

• Crohn's disease, ulcerative colitis

• chloasma

**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 HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Microlite

Keep this medicine out of the sight and reach of children.
Do not store above 30°C

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

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

## 6. Contents of the pack and other information

**What Microlite contains**

- The active substances are levonorgestrel and ethinylestradiol.
- Each coated tablet contains 100 microgram levonorgestrel and 20 microgram ethinylestradiol.

- The other ingredients are:

- Tablet core: lactose monohydrate, maize starch, pregelatinized maize starch, povidone and magnesium stearate (E470b)
- Tablet coating: sucrose, povidone, macrogol 6000, calcium carbonate, talc (E553b), glycerol 85%, montanglycol wax, titanium dioxide (E171), iron oxide yellow (E172) and iron oxide red (E172).

**What Microlite looks like and contents of the pack**

- Microlite are pink, round, coated tablets.

- Microlite is available in packs of 1, 3, 6 and 13 blister packs each with 21 coated tablets.

**Marketing Authorisation Holder**
Bayer Limited, 1st Floor, The Grange Offices, The Grange, Brewery Road, Stillorgan, Co. Dublin, A94 H2K7, Ireland

**Manufacturer**
Bayer AG
Müllerstraße 178
13353 Berlin
Germany

**This medicine is authorised in the Member States of the European Economic Area under the following names:**

Germany, Netherlands and Portugal: **Miranova**
Ireland: **Microlite**

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