Package leaflet: Information for the user

Mercilon® Tablets 150mcg/20 microgram Tablets

Desogestrel
Ethinylestradiol

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 using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, or your 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What is Mercilon and what is it used for?
   1.1 Composition and type of Pill
   1.2 Why use Mercilon
2. What you need to know before you use Mercilon
   2.1 When you should not use Mercilon
   2.2 When to take special care with Mercilon
   2.3 When should you contact your doctor
3. How to use Mercilon
   3.1 When and how to take the tablets
   3.2 Starting your first pack of Mercilon
   3.3 If too many Mercilon tablets are taken (overdose)
   3.4 What to do if
   3.5 If you want to stop taking Mercilon
4. Possible side effects
5. How to store Mercilon
6. Further information
   6.1 What Mercilon contains
   6.2 What Mercilon looks like and content of the pack
   6.3 Marketing Authorisation Holder and Manufacturer
   6.4 Last revision of this package leaflet.

1. WHAT IS MERCILON AND WHAT IS IT USED FOR?

1.1 Composition and type of Pill

MERCILON is a combined oral contraceptive ('the combined Pill'). Each tablet contains a small amount of two different female hormones. These are desogestrel (a progestogen) and ethinylestradiol (an estrogen). Because of the small amounts of hormone, MERCILON is considered a low-dose oral contraceptive. As all

tablets in the pack combine the same hormones in the same dose, it is considered a monophasic combined oral contraceptive.

1.2 Why use Mercilon?

MERCILON is used to prevent pregnancy. When taken correctly (without missing tablets), the chance of becoming pregnant is very low.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE MERCILON

General notes

Before you start using Mercilon 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".

In this leaflet, several situations are described where you should stop taking the Pill, or where the reliability of the Pill may be decreased. In such situations you should not have sexual 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 the Pill alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

Mercilon, like all contraceptive Pills, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

Mercilon has been prescribed for you personally. Do not share it with others.

Mercilon should normally not be used to delay a period. However, if in exceptional cases you need to delay a period, contact your doctor.

2.1 When you should not use MERCILON

You should not use MERCILON 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. See also section 2.2 'When to take special care with Mercilon'.

- 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 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 had a pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood.
- if you have jaundice (yellowing of the skin) or severe liver disease.
- if you have or have had a cancer that may grow under the influence of sex hormones (e.g., of the breast or the genital organs).
- if you have or have had a benign or malignant liver tumour.

- if you have any unexplained vaginal bleeding.
- if you have endometrial hyperplasia (abnormal growth of the lining of the womb)
- if you are pregnant or think you might be pregnant.
- if you are allergic (hypersensitive) to desogestrel or ethinylestradiol, or any of the other ingredients of this medicine (listed in section 6).
- if you have Hepatitis C and are taking medicinal products containing ombitasvir /paritaprevir / ritonavir and dasabuvir (see also section "Other medicines and Mercilon").

If any of these conditions appear for the first time while using the Pill, stop taking it at once and consult your doctor. In the meantime, use a non-hormonal contraceptive. See also 'General Notes' above.

2.2 When to take special care with MERCILON
Before you can begin taking Mercilon, 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.

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.
If the condition develops, or gets worse while you are using Mercilon, you should also tell your doctor.
- if you smoke;
- if you have diabetes;
- if you are overweight;
- if you have high blood pressure;
- if you have a heart valve disorder or a certain heart rhythm disorder;
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- if you have varicose veins;
- if anyone in your immediate family has had a thrombosis, a heart attack or a stroke;
- if you suffer from migraine;
- if you suffer from epilepsy;
- 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 Mercilon;
- if anyone in your immediate family has had breast cancer;
- if you have liver or gallbladder disease;
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- if you have systemic lupus erythematosus (SLE; a disease affecting your natural defense system);
- if you have haemolytic uraemic syndrome (HUS- a disorder of blood coagulation causing failure of the kidneys);
- if you have sickle cell anaemia (an inherited disease of the red blood cells);
- if you suffer from asthma
- if you suffer from an endogenous depression (a depression which is not caused by external factors)

- if you have a condition that occurred for the first time or worsened during pregnancy or previous use of sex hormones (e.g., hearing loss, a metabolic disease called porphyria, a skin disease called herpes gestationis, a disease called Sydenham's chorea);
- 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 estrogens may cause or worsen the symptoms of hereditary and acquired angioedema.
    - if you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet light.

If any of the above conditions appear for the first time, come back or get worse while using the Pill, you should contact your doctor.

Psychiatric Disorders
Some women using hormonal contraceptives including Mercilon 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.

2.2.1 The Pill and Thrombosis

BLOOD CLOTS
Using a combined hormonal contraceptive such as Mercilon, 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 Mercilon 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:
  • pain or tenderness in the leg which may be felt only when standing or walking
  • increased warmth in the affected leg
  • change in colour of the skin on the leg e.g. turning pale, red or blue
	Deep vein thrombosis

• sudden unexplained breathlessness or rapid breathing; • sudden cough without an obvious cause, which may bring up blood; • sharp chest pain which may increase with deep breathing; • severe light headedness or dizziness; • rapid or irregular heartbeat; • severe pain in your stomach; 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: • immediate loss of vision or • painless blurring of vision which can progress to loss of vision	Retinal vein thrombosis (blood clot in the eye)
• chest pain, discomfort, pressure, heaviness; • sensation of squeezing or fullness in the chest, arm or below the breastbone; • fullness, indigestion or choking feeling; • upper body discomfort radiating to the back, jaw, throat, arm and stomach; • sweating, nausea, vomiting or dizziness; • extreme weakness, anxiety, or shortness of breath; • rapid or irregular heartbeats	Heart attack
• sudden weakness or numbness of the face, arm or leg, especially on one side of the body; • sudden confusion, trouble speaking or understanding; • sudden trouble seeing in one or both eyes; • sudden trouble walking, dizziness, loss of balance or coordination; • sudden, severe or prolonged headache with no known cause; • loss of consciousness or fainting with or without seizure. 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.	Stroke
• swelling and slight blue discolouration of an extremity; • 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 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 Mercilon 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 Mercilon 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 desogestrel such as Mercilon 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 **not using** 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 **levonorgestrel, norethisterone or norgestimate**	About 5-7 out of 10,000 women
Women using Mercilon	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 Mercilon 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 Mercilon may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Mercilon 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 Mercilon needs to be stopped.

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

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

2.2.2 The Pill and Cancer
Breast cancer has been diagnosed slightly more often in women who use the Pill than in women of the same age who do not use the Pill. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after stopping use of the Pill. It is not known whether the difference is caused by the Pill. It may be that the women were examined more often, so that the breast cancer was noticed earlier.

In rare cases benign liver tumours and even more rarely, malignant liver tumours have been reported in users of the Pill. These tumours may lead to internal bleeding. Contact your doctor immediately if you have severe pain in your abdomen.

Cervical cancer is caused by an infection with the human papilloma virus. It has been reported to occur more often in women using the Pill for a long time. It is unknown if this finding is due to the use of hormonal contraceptives or to sexual behaviour and other factors (such as better cervical screening).

2.2.3 The Pill and using Other Medicines

Always tell your doctor which medicines or herbal products you are already using. Also tell any other doctor or dentist (or the pharmacist) who prescribes another medicine that you take Mercilon. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long, or whether the use of another medicine you need must be changed.

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

Some medicines
- ***can have an influence on the blood levels of Mercilon***
- ***can make it less effective in preventing pregnancy***
- ***can cause unexpected bleeding***

These include medicines used for the treatment of:
- epilepsy (e.g. primidone, phenytoin,phenobarbital, carbamazepine, oxcarbazepine, topiramate, felbamate,);
- tuberculosis (e.g. rifampicin, rifabutin);
- HIV infections (e.g. ritonavir, nelfinavir, nevirapine, efavirenz);
- Hepatitis C virus infection (e.g., boceprevir, telaprevir);
- other infectious diseases (e.g., griseofulvin);
- high blood pressure in the blood vessels of the lungs (bosentan);
- depressive moods (the herbal remedy St. John's wort).

If you are taking medicines or herbal products that might make Mercilon less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on Mercilon may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive method for that long.

Mercilon may ***influence the effect of*** other medicines, ***e.g.***
- ***medicines containing ciclosporine***
- ***the anti-epileptic lamotrigine (This could lead to an increased frequency of seizures)***

2.2.4 The Pill and Pregnancy
MERCILON must not be used by women who are pregnant, or who think they may be pregnant. If you suspect that you are pregnant while you are already using MERCILON, you should consult your doctor as soon as possible.

2.2.5 The Pill and Breastfeeding
MERCILON is generally not recommended for use during breastfeeding. If you wish to take the Pill while breastfeeding, please ask your doctor.

2.2.6 The Pill and Driving and Using machines
There are no observed effects.

2.2.7 Important information about some of the ingredients of Mercilon
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before starting with Mercilon.

2.2.8 Use in children and adolescents
No clinical data on efficacy and safety are available in adolescents below 18 years.

2.3 WHEN SHOULD YOU CONTACT YOUR DOCTOR?

Regular check-ups
When you are using the Pill, you should see your doctor regularly at least every 6 –12 months.
If you have any unusual symptoms such as unexplained pains in the chest, abdomen or legs you must consult your doctor immediately.

Contact your doctor as soon as possible 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 above).
  For a description of the symptoms of these serious side effects please go to "How to recognise a blood clot".
- you notice any changes in your own health, especially involving any of the items mentioned in this leaflet (see also section 2.1 '*When you should not use MERCILON* and section 2 '*What you need to know before you use MERCILON'*; do not forget about changes in the health of your immediate family);
- you feel a lump in your breast;
- you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also in section 2.2 'When to take special care with Mercilon');
-
- you are going to use other medications (see also section 2.2.3 '*The Pill and using Other Medicines'*);
- you are to be immobilised or are to have surgery (consult your doctor at least four weeks in advance);
- you have unusual, heavy vaginal bleeding;
- you forgot tablets in the first week of the pack and had intercourse in the seven days before;
- you have severe diarrhoea;
- you miss your period twice in a row or suspect you are pregnant (do not start the next pack until told to by your doctor).

3. HOW DO YOU USE MERCILON?

3.1 When and how to take the tablets?

The Mercilon pack contains 21 tablets. On the pack, each tablet is marked with the day of the week on which it is to be taken. Take your tablet at about the same time each day, with some water if necessary. Follow the direction of the arrows until all 21 tablets have been taken. During the next 7 days you take no tablets. A period should begin during these 7 days (the withdrawal bleed). Usually it will start on day 2-3 after the last MERCILON tablet. Start taking your next pack on the 8th day even if your period continues. This means that you will always start new packs on the same day of the week, and also that you have your withdrawal bleed on about the same days, each month.

<u>Use in children and adolescents</u>
No clinical data on efficacy and safety are available in adolescents below 18 years.

3.2 Starting your first pack of MERCILON

- *When no hormonal contraceptive has been used in the past month.*
  Start taking MERCILON on the first day of your cycle, i.e. the first day of menstrual bleeding. Take a tablet marked with that day of the week. For example, if your period starts on a Friday, take a tablet marked Friday. Then follow the days in order. MERCILON will work immediately, it is not necessary

to use an additional contraceptive method. You may also start on days 2-5 of your cycle, but in that case make sure you also use an additional contraceptive method (barrier method) for the first 7 days of tablet-taking in the first cycle.

- *When changing from another combined hormonal contraceptive (combined oral contraceptive pill (COC), vaginal ring, or transdermal patch).*
  You can start taking MERCILON the day after you take the last tablet from your present Pill pack (this means no tablet-free break). If your present Pill pack also contains inactive tablets you can start MERCILON on the day after taking the last **active** tablet (if you are not sure which this is, ask your doctor or pharmacist). You can also start later, but never later than the day following the tablet-free break of your present Pill (or the day after the last inactive tablet of your present Pill). In case you use a vaginal ring or transdermal patch, it is best that you start using MERCILON on the day you remove the ring or patch. You can also start at the latest, on the day you would have started using the next ring or patch. If you follow these instructions, it is not necessary to use an additional contraceptive method.

- *When changing from a progestogen-only pill (minipill).*
  You can stop taking the minipill any day and start taking MERCILON the next day, at the same time. But make sure you also use an additional contraceptive method (a barrier method) for the first 7 days that you are taking Mercilon.

- *When changing from an injectable, an implant or a progestogen-releasing intrauterine device (IUD).*
  Start using MERCILON when your next injection is due or on the day that your implant or your IUD is removed. But make sure you also use an additional contraceptive method (a barrier method) for the first 7 days that you are taking Mercilon.

- *After having a baby.*
  You can start MERCILON between 21 and 28 days after having a baby. If you start later than day 28, you must use a so-called barrier method (for example, a condom) during the first 7 days of MERCILON use. If, after having a baby, you have had sexual intercourse before starting MERCILON (again), you must first be sure that you are not pregnant or you must wait until your next period.

  If you are breast-feeding and want to take MERCILON, read section 2.2.5 “The Pill and Breastfeeding”.

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

- *After a miscarriage.*
  Follow the advice of your doctor.

3.3 If too many MERCILON tablets are taken (overdose)

There have been no reports of serious harmful effects from taking too many Mercilon tablets at one time. If you have taken several tablets at a time, you may have nausea, vomiting or vaginal bleeding. If you discover that a child has taken MERCILON, ask your doctor for advice.

3.4 WHAT TO DO IF…….

.....you forget tablets

- If you are **less than 12 hours late** in taking a tablet, the reliability of the Pill is maintained. Take the tablet as soon as you remember and take the next tablets at the usual times.

- If you are **more than 12 hours late** in taking any tablet, the reliability of the Pill may be reduced. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is

decreased. There is a particularly high risk of becoming pregnant if you miss tablets at the beginning or at the end of the pack. Therefore you should follow the rules given below.

More than one tablet forgotten in a pack
Ask your doctor for advice.

1 tablet missed in week 1
Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time. Use extra contraceptive precautions (barrier method) for the next 7 days. If you had sexual intercourse in the week before missing the tablets, there is a possibility of becoming pregnant. So tell your doctor immediately.

1 tablet missed in week 2
Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time. The reliability of the Pill is maintained. You need not use extra contraceptive precautions.

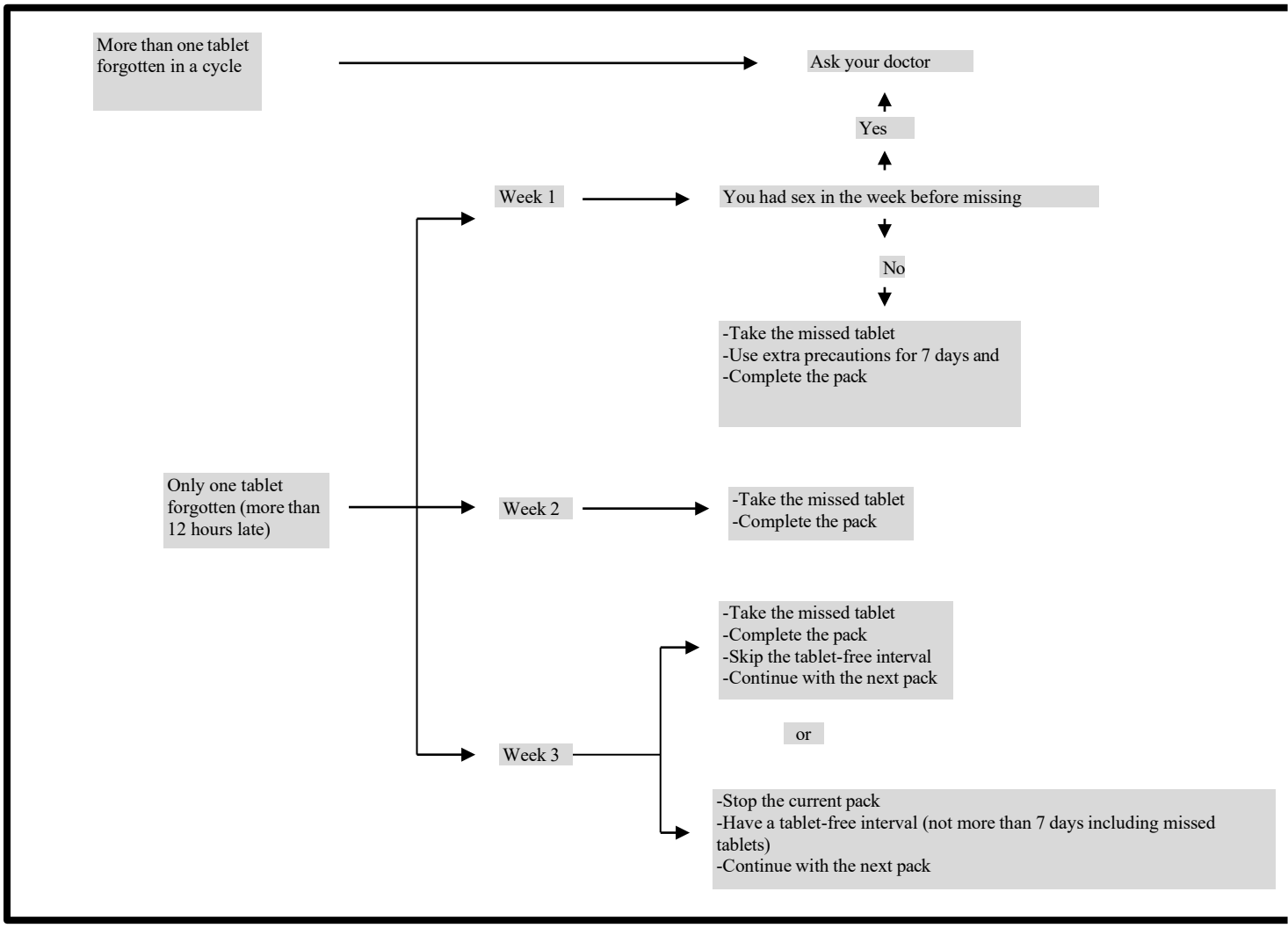
1 tablet missed in week 3
You may choose either of the following options, without the need for extra contraceptive precautions.

1. Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time. Start the next pack as soon as the current pack is finished so that **no gap is left between packs**. You may not have a withdrawal bleed until the end of the second pack but you may have spotting or breakthrough bleeding on tablet-taking days.

Or

2. Stop taking tablets from your current pack, have a tablet-free break of 7 days or less (**including the day you missed your tablet**) and then start with the next pack. If you do this, you can always start your next pack on the same day of the week as you usually do.

- If you have forgotten tablets in a pack and you do not have the expected period in the first normal tablet-free break, you may be pregnant. Consult your doctor before you start with the next pack.



WHAT TO DO IF…….

…..you suffer from gastro-intestinal disturbances (e.g., vomiting, severe diarrhoea)
If you vomit, or have severe diarrhoea, the active ingredients of your MERCILON tablet may not have been completely absorbed. If you vomit within 3 to 4 hours after taking your tablet, this is like missing a tablet. Therefore, follow the advice for missed tablets. If you have severe diarrhoea, please tell your doctor.

…..you want to delay your period
You can delay your period if you start with your next pack of Mercilon immediately after finishing your current pack. You can continue with this pack for as long as you wish, until this pack is empty. When you wish your period to begin, just stop tablet-taking. While using the second pack you may have some breakthrough bleeding or spotting on tablet-taking days. Start with your next pack after the usual 7-day tablet-free break.

…..you want to change the starting day of your period
If you take your tablets correctly, you will have your period on about the same day every 4 weeks. If you want to change this, just shorten, (never lengthen) the next tablet-free break. For example, if your period usually starts on a Friday and in future you want it to start on Tuesday (3 days earlier) you should now start your next pack 3 days sooner than you usually do. If you make your tablet-free break very short (e.g. 3 days or less), you may not have a bleeding during the break. You may have some breakthrough bleeding or spotting during the use of the next pack.

. you have unexpected bleeding
With all Pills, for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection, but keep taking your tablets as usual. Irregular vaginal bleeding usually stops once your body has adjusted to the Pill (usually after about 3 tablet-taking cycles). If it continues, becomes heavy or starts again, tell your doctor.

…..you have missed a period
If you have taken all of your tablets at the right time, and you have not vomited, nor had severe diarrhoea or used other medicines then you are very unlikely to be pregnant. Keep taking MERCILON as usual.

If you miss your period twice in a row, you may be pregnant. Tell your doctor immediately. Do not start the next pack of Mercilon until your doctor has checked you are not pregnant.

3.5 If you want to stop taking MERCILON

You can stop taking MERCILON at any time you want. If you do not want to become pregnant, ask your doctor about other methods of birth control.
If you stop taking Mercilon because you want to get pregnant, it is generally recommended that you wait until you have had a natural period before trying to conceive. This helps you to work out when the baby will be due.

4. POSSIBLE SIDE EFFECTS

Like all medicines, MERCILON 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 Mercilon, please talk to your doctor.

An increased risk of blood clots in your veins (venous thromboembolism (VTE)) or blood clots in your arteries (arterial thromboembolism (ATE)) is present for all women taking 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 use Mercilon".

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 "What you need to know before you use Mercilon").

Please read these sections for additional information and consult your doctor at once where appropriate.

The following side effects have been reported by users of the Pill, although they need not be caused by the Pill. These side effects may occur in the first few months that you are using the Pill and usually lessen with time.

Common (occurring in more than one per 100 women):
- depressed mood, mood changes;
- nausea, abdominal pain;
- increase in body weight,
- headache;
- breast pain, breast tenderness;

Uncommon (occurring in more than one per 1000 women but not more than one per 100 women):
- fluid retention
- decreased sexual drive
- migraine
- vomiting, diarrhoea
- rash, hives
- breast enlargement

Rare (occurring in less than one per 1000 women):

- 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.)

- hypersensitivity reactions;
- increased sexual drive;
- contact lens intolerance;
- erythema nodosum, erythema multiforme (these are skin conditions).
- breast secretion; vaginal secretion
- decrease in body weight

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.
Ireland: HPRA Pharmacovigilance, Website: www.hpra.ie.
Malta: ADR Reporting at: www.medicinesauthority.gov.mt/adrportal.

5. HOW TO STORE MERCILON

Keep your tablets out of reach and sight of children!

Store Tablets below 25°C. Keep your tablets in the original package in order to protect from light. Do not use Mercilon tablets after the expiry date which is stated on the carton, blister and sachet. The expiry date refers to the last day of the month.

Do not use the product if you notice, for example, colour change in the tablet, crumbling of the tablet or any other visible signs of deterioration.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

6.1 What Mercilon contains

The active substances are:
Each Tablet contains 150 micrograms of Desogestrel and 20 micrograms of Ethinylestradiol

The other ingredients are:
Tablet Core:
all-rac-alpha-tocopherol
lactose monohydrate;
potato starch;
povidone
Silica colloidal anhydrous;

stearic acid

6.2 What Mercilon looks like and content of the pack
MERCILON is presented in 3 strips of 21 tablets packed in a ply carton. The white tablets are biconvex, round and 6mm in diameter. Each tablet is coded on one side 'Organon' and an asterix '*' and on the reverse side 'TR' above '4'.

6.3 Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder Ireland:
Organon Pharma (Ireland) Limited
2 Dublin Landings
North Wall Quay - North Dock
Dublin, D01 V4A3
Ireland

Marketing Authorisation Holder Malta:
N.V. Organon
Kloosterstraat 6
NL-5349 AB Oss
The Netherlands

Manufacturer
NV Organon, P.O. Box 20, 5340 BH OSS, The Netherlands

6.4 Last revision of this package leaflet
This PIL was last revised/approved in September 2022.

© 2021 Organon group of companies. All rights reserved.