

USER PACKAGE LEAFLET FOR MERCILON®

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 any further questions, please 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 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.

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

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 hormones, 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.

Why use Mercilon®?

Mercilon® is used to prevent pregnancy.

When taken correctly (without missing tablets), the chance of becoming pregnant is very low.

2. BEFORE YOU START TO USE MERCILON®

2.1 When should you not use Mercilon®?

Do not use the combined Pill if you have any of the conditions listed below. If anything on this list applies to you, tell your doctor before starting to use Mercilon®. Your doctor may advise you to use a different type of Pill or an entirely different (non-hormonal) method of birth control.

- If you have, or have had in the past a blood clot (thrombosis) in a blood vessel of the leg, lung (embolus) or other organs.
- If you have or have had in the past a heart attack or stroke.
- If you have or have ever had a condition that may be a first sign of a heart attack (such as angina pectoris or chest pain) or stroke (such as transient ischaemic attack or small reversible stroke).
- If you have a disturbance of blood clotting (for example, protein C deficiency).
- If you have major surgery (e.g., an operation) and your ability to move around is limited for a long period of time (see section 2.2.3 'The Pill and Thrombosis').
- If you have (had) a type of migraine called 'migraine with aura'.
- If you have diabetes mellitus with blood vessel damage.
- If you have a serious risk factor, or several risk factors for developing thrombosis, this may also be a reason why you cannot use Mercilon® (see also section 2.2.3 'The Pill and Thrombosis').
- 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 have (had) severe liver disease and your liver is not yet working normally.
- 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 liver tumour.
- If you have any unexplained vaginal bleeding.
- If you are pregnant or think you might be pregnant.
- If you are allergic to any of the ingredients of Mercilon®.
- If you have very high blood pressure.
- If you have excessive thickening of the womb lining.
- If you have a blood disease called porphyria.
- If you have high fat levels in your blood (high cholesterol or triglyceride levels).
- If you have had any of the following problems while pregnant or while using steroids:
 - itching of the whole body (pruritus)

- blister-like rash, called herpes gestationis

If any of these conditions appear for the first time while using the Pill, stop taking it at once and tell your doctor. In the meantime, use non-hormonal contraceptive. See also 'General Notes' in section 2.2.1.

Do not use Mercilon® if you have Hepatitis C and are taking the combination drug regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir (see section 2.2.5 'The Pill and using Other Medicines').

2.2 When do you need to take special care with Mercilon®?

2.2.1 General notes

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.

2.2.2 What do you need to know before using Mercilon®?

If the combined Pill is used in the presence of any of the conditions listed below you may need to be kept under close observation. Your doctor can explain this to you. Therefore, if any of these apply to you, tell your doctor before starting to use Mercilon®.

- you smoke;
- you have diabetes;
- you are overweight;
- you have high blood pressure;
- you have a heart valve disorder or a certain heart rhythm disorder;
- you have an inflammation of your veins (superficial phlebitis);
- you have varicose veins;
- anyone in your immediate family has had a thrombosis, a heart attack or a stroke;
- you suffer from migraine;
- you suffer from epilepsy;
- you or someone in your immediate family have or have had high cholesterol or triglycerides (fats in the blood);
- anyone in your immediate family has had breast cancer;
- you have liver or gallbladder disease;
- you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);

- you have systemic lupus erythematosus (SLE; a chronic connective tissue disease affecting the skin all over the body);
- you have haemolytic uraemic syndrome (HUS; a disorder of blood clotting causing failure of the kidneys);
- you have sickle cell disease (a rare blood disease);
- you have an operation, or if your ability to move around is limited for a long period of time (see section 2.2.3 'The Pill and Thrombosis');
- if you have recently given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start using Mercilon® (see section 2.2.3 'The Pill and Thrombosis');
- you have a condition that occurred for the first time or worse during pregnancy or previous use of sex hormones (e.g., hearing loss, a disease called porphyria, a skin disease called herpes gestationis, a disease called Sydenham's chorea); hereditary and acquired angioedema [*you should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives, potentially with difficulty breathing*]. Products containing estrogens may cause or worsen hereditary and acquired angioedema;
- 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 radiation.

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.

2.2.3 The Pill and Thrombosis

A thrombosis is the formation of a blood clot which may block a blood vessel.

A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this blood clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called 'pulmonary embolism'. Deep venous thrombosis is a rare occurrence. It can develop whether or not you are taking the Pill. The risk is higher in Pill-users than in non-users. The chance of getting a thrombosis is highest during the first year after you start using the Pill for the very first time. The risk is also higher if you restart using the Pill (the same product or a different product) after a break of 4 weeks or more. The risk is not as high as the risk of developing a thrombosis during pregnancy.

The risk of getting a deep venous thrombosis for women using Pills with desogestrel may be slightly higher than for women using Pills with levonorgestrel. The absolute numbers remain very small. If 10 000 women use a Pill with levonorgestrel for one year, 2 women would get a thrombosis. If 10 000 women use a Pill with desogestrel for a year approximately 3 to 4 women would get a thrombosis. For comparison, if 10 000 women get pregnant, approximately 5-20 would get a thrombosis. These findings are based on the results of some studies. Other studies did not find a higher risk for Pills with desogestrel.

Blood clots can also occur very rarely in an artery (arterial thrombosis); for example, in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke).

Extremely rarely blood clots can occur in the liver, gut, kidney or eye.

Very occasionally a thrombosis may cause serious permanent disabilities or may even be fatal.

The risk of venous thrombosis in users of combined pills increases:

- with increasing age,
- if you are overweight,
- if one of your close relatives has had a blood clot (thrombosis) in the leg, lung, or other organ at a young age,
- if you must have an operation, if your ability to move around is limited for long period of time, or if you have had a serious accident. It is important to tell your doctor in advance that you are using Mercilon® as the treatment may have to be stopped. Your doctor will tell you when to start Mercilon® again. This is usually about two weeks after you are able to move around. See also section 2.1 'When should you not use Mercilon®'.
- if you gave birth less than a few weeks ago.

The risk of arterial thrombosis in users of combined pills increases:

- if you smoke. You are strongly advised to stop smoking when you use Mercilon®, especially if you are older than 35 years.
- if you have an increased fat content in your blood (cholesterol or triglycerides)
- if you have high blood pressure
- if you have migraine
- if you have a problem with your heart (valve disorder, a disturbance of the heart rhythm)

If you notice possible signs of a thrombosis, stop taking the Pill and consult your doctor immediately (see also 'When should you contact your doctor?').

2.2.4 The Pill and Cancer

The information given below was obtained from studies of women who used combined oral hormonal contraceptives, such as the combined pill, and from an additional study that included both oral and non-oral hormonal contraceptive-users.

In studies with the combined pill, 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 the additional study that included both oral and non-oral hormonal contraceptive-users, the occurrence of breast cancer was reported to increase the longer the women used the contraceptive. The difference in the reported risk of breast cancer between women who had never used the contraceptive and those who had used the contraceptive was small: 13 additional cases of breast cancer per 100,000 women-years.

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).

2.2.5 The Pill and using Other Medicines

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines or herbal products, even those not prescribed. Also tell any other doctor or dentist who prescribes another medicine (or your pharmacist) that you use Mercilon®.

Some medicines may stop Mercilon® from working properly. 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 also interfere with how other medicines work, causing either an increase in effect (e.g., ciclosporin) or a decrease in effect (e.g., lamotrigine).

Do not use Mercilon® if you have Hepatitis C and are taking the combination drug regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir as this may cause increases in liver function blood test results (increase in ALT liver enzyme). Mercilon® can be restarted approximately 2 weeks after completion of treatment with the combination drug regimen (see section 2.1 'When should you not use Mercilon®?').

If you are taking other Hepatitis C drug combinations (such as glecaprevir/pibrentasvir) you may experience increased levels of the liver enzyme 'alanine aminotransferase' (ALT) in the blood.

Laboratory tests

If you are having any blood or urinary test, tell your health care professional that you are using Mercilon® as it may affect the results of some tests.

2.2.6 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 tell your doctor as soon as possible.

2.2.7 The Pill and Breast-feeding

Mercilon® is not usually recommended for use during breast-feeding. If you wish to take the Pill while breast-feeding, please ask your doctor.

2.2.8 The Pill and Driving and Using machines

There are no observed effects.

2.2.9 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®.

2.3 When should you contact your doctor?

Regular check-ups

When you are using the Pill, your doctor will tell you to return for regular check-ups. You should usually have a check-up every year.

Contact your doctor as soon as possible if:

- you notice any changes in your own health, especially involving any of the items mentioned in this leaflet (see also section 2.1 'When should you not use Mercilon®?' and section 2.2.2 'What do you need to know before using 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 2.2.2 'What do you need to know before using Mercilon®?');
- you are going to use other medications (see also section 2.2.5 'The Pill and using other medicines');
- your ability to move around is limited for a long period of time or you are to have surgery (tell your doctor at least 4 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 your doctor tells you).

Stop taking tablets and see your doctor immediately if you notice possible signs of thrombosis, myocardial infarction or a stroke:

- an unusual cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe or prolonged headache or migraine attack;
- partial or complete loss of vision, or double vision;
- slurring or speech disability;
- sudden changes to your hearing, sense of smell or taste;
- dizziness or fainting;
- weakness or numbness in any part of your body;
- severe pain in your abdomen;
- severe pain or swelling in either of your legs.

For more information, see section 2.2.3 in this leaflet.

2.4 More about hormonal contraceptives

The combined Pill may also have non-contraceptive health benefits.

- Your period may be lighter and shorter. As a result, the risk of anaemia may be lower. Your period pains may become less severe or may completely disappear.
- In addition, some serious disorders have been reported to occur less frequently in users of Pills containing 50 µg of ethinylestradiol ('high-dose Pills'). These are benign breast disease, ovarian cysts, pelvic infections (pelvic inflammatory disease or PID), ectopic pregnancy (pregnancy in which the embryo implants outside of the uterus) and cancer of the endometrium (lining of the womb) and ovaries. This may also be the case for low-dose Pills but so far this has not been confirmed.

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 liquid 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.

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 if you do, 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 to 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 have used the Pill, patch or ring consistently and correctly and if you are sure that you are not pregnant, you can also stop taking the Pill or remove the ring or patch on any day and start using Mercilon® immediately.

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 if you are having intercourse, 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 a progestogen-only injectable, 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 IUD is removed. But if you are having intercourse, 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*

If you have just had a baby, your doctor may tell you to wait until after your first normal period before you start taking Mercilon®. Sometimes it is possible to start sooner. Your doctor will advise you. If you are breast-feeding and want to take Mercilon®, you should talk to your doctor first.

- *After a miscarriage or an abortion*

Your doctor will advise you.

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 (see also the diagram 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, it's possible that you could be 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

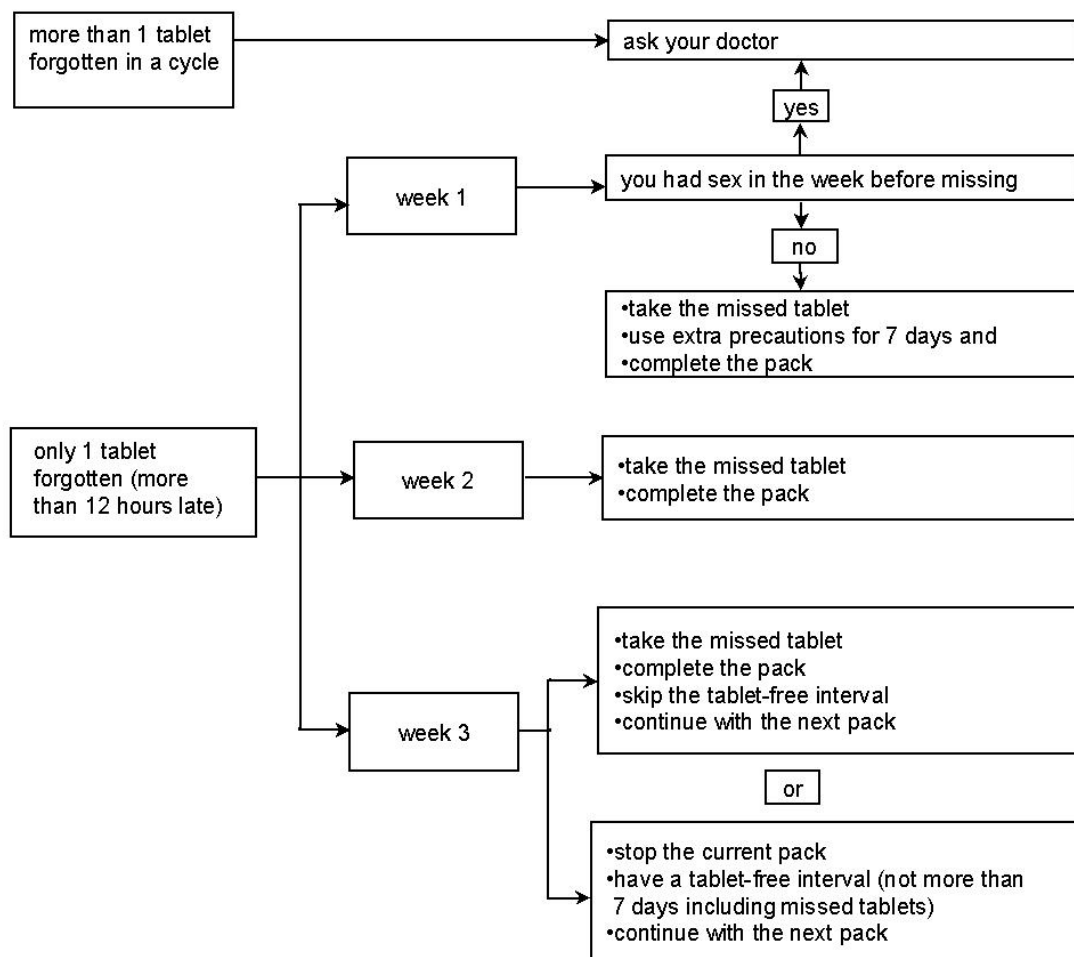
You may choose either of the following options, without the need for extra contraceptive precautions.

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 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 your period in the first normal tablet-free break, you may be pregnant. Tell your doctor before you start with the next pack.



...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. You must 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 day, 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), start your next pack 3 days sooner than you usually do. If you make your tablet-free period very short (e.g., 3 days or less), you may not bleed during the break. You may have some breakthrough bleeding or spotting during 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 months). If bleeding 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, 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, you should 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 have side effects, although not everybody gets them.

Tell your doctor if you notice any unwanted effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by the Pill.

Serious reactions seen with the Pill, as well as the related symptoms, are described in the sections 2.2.3 and 2.2.4: 'The Pill and Thrombosis/The Pill and Cancer'.

Common (occurring in more than one per 100 users):

- Depressed mood, mood changes
- Headache
- Nausea, abdominal pain
- Breast pain, breast tenderness
- Increase in body weight

Uncommon (occurring in more than one per 1000 users but not more than one per 100 users):

- Fluid retention
- Decreased sexual drive
- Migraine
- Vomiting, diarrhea
- Rash, hives
- Breast enlargement

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

- Contact lens intolerance
- Hypersensitivity reactions
- Blood clot in a vein
- Blood clot in an artery
- Decrease in body weight
- Increased sexual drive
- Breast secretion
- Vaginal secretion
- Erythema nodosum, erythema multiforme (these are skin conditions)

Unknown (frequency cannot be estimated from the available data):

- Angioedema, particularly in patients who already have a (family) history of angioedema

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

5. HOW TO STORE MERCILON®

Do not use after the expiry date stated on the package.

Store your tablets at or below 30°C in the original package. Do not freeze.

Store protected from light and moisture.

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.

Keep your tablets out of the reach of children!

6. FURTHER INFORMATION

6.1 What Mercilon® contains

- The active substances are:
Ethinyl estradiol (0.020 mg) and desogestrel (0.150 mg)
- The other ingredients are:
Silica colloidal anhydrous; lactose monohydrate; potato starch; povidone; stearic acid; all-*rac-alpha*-tocopherol.

6.2 What Mercilon® looks like and content of the pack

Mercilon® comes in 1, 3 or 6 strips of 21 tablets packed in a ply carton.

The tablets are biconvex, round and 6 mm in diameter. Each tablet is marked TR above 4 on one side and Organon* on the reverse side.

Not all presentations may be available locally.

6.3 Product Registrant

Organon Singapore Pte. Ltd.

150 Beach Road

#36-01/08 Gateway West

Singapore 189720

6.4 Last revision of this package leaflet

June 2022

IF YOU HAVE ANY FURTHER QUESTIONS OR REQUIRE THE FULL PRESCRIBING INFORMATION FOR MERCILON®, PLEASE CONSULT YOUR DOCTOR OR PHARMACIST.

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