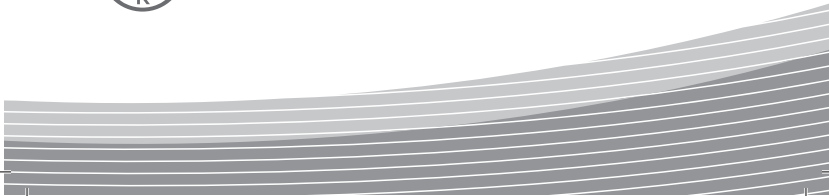




Microgynon 30



**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

Microgynon[®] 30

Film-coated Tablets

Each tablet contains:
levonorgestrel 0.15 mg
ethinylestradiol 0.03 mg

Inactive and allergenic ingredients: see section 6 “Further information”.

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

ESSENTIAL INFORMATION ABOUT COMBINED HORMONAL CONTRACEPTIVES AND ABOUT THE MEDICINE

- When used correctly, combined hormonal contraceptives are considered one of the most reliable reversible methods of contraception.
- They slightly increase the risk of a blood clot in the veins and arteries, especially in the first year or when resuming treatment with a combined hormonal contraceptive after a break of 4 or more weeks.
- Be alert and refer to a doctor if you think you have symptoms of a blood clot (see “Blood clots” in section 2).

- When taken for an extended period, oral contraceptive pills may reduce your risk of cancer of the ovaries and womb.
- Oral contraceptive pills do not protect against sexually transmitted diseases such as AIDS (HIV) or chlamydia; only a condom can help with this.
- This medicine may increase your risk of effects such as blood clots and breast cancer.
- There are some women for whom oral contraceptive pills are not suitable because of their medical condition. Please read this leaflet to make sure that Microgynon 30 is right for you.
- To prevent pregnancy, it is important to take Microgynon 30 as instructed and to start each strip on time. Please make sure that you understand what to do if you forgot a tablet or if you think you are pregnant.

1) WHAT IS THE MEDICINE INTENDED FOR?

Microgynon 30 is intended to prevent pregnancy.

Therapeutic group: Microgynon 30 belongs to a group of medicines called combined pills (oral contraceptive pills) that contain 2 types of female hormones: estrogen and progestogen. These hormones prevent pregnancy in 3 ways: by preventing release of an egg from the ovaries, thickening the discharge from the cervix which makes it more difficult for sperm to penetrate the womb and preventing thickening of the lining of the womb required for implantation of the egg.

- When used correctly, oral contraceptive pills are considered one of the most reliable, reversible contraceptive methods.
- Oral contraceptive pills do not interrupt sexual intercourse.
- Oral contraceptive pills usually make menstrual cycles regular, lighter and less painful.
- Oral contraceptive pills may relieve pre-menstrual symptoms.

2) BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to levonorgestrel or to ethinylestradiol or to any of the other ingredients contained in the medicine. For the list of inactive ingredients, see section 6 “Further information”.
- you are pregnant or suspect that you are pregnant (see section 2 “Pregnancy, breastfeeding and fertility”).
- you are suffering, or have suffered in the past, from a blood clot in the blood vessels of your legs (deep vein thrombosis, DVT), in your lungs (pulmonary embolism, PE), or in other organs of the body.

- you know you are suffering from a blood clotting disorder (e.g., protein C deficiency, protein S deficiency, antithrombin III deficiency, factor V Leiden or antiphospholipid syndrome).
- you need to undergo surgery or if you are immobile for a long time (see “Blood clots” in section 2).
- you have suffered in the past from a heart attack or a stroke.
- you are suffering, or have suffered in the past, from angina pectoris (a condition that causes severe chest pain and can be a first sign of heart attack) or from transient ischemic attack (TIA – temporary stroke symptoms).

- you are suffering from one of the following diseases that may increase your risk of arterial blood clot:
 - severe diabetes with blood vessel damage
 - very high blood pressure
 - very high blood fat levels (cholesterol or triglycerides)
 - a medical condition characterized by high blood homocysteine levels (hyperhomocysteinemia)
- you are suffering, or have suffered in the past, from a type of migraine called “migraine with aura”.

- you are suffering, or have suffered in the past, from breast cancer.
- you have suffered in the past from a severe liver disease, and you have been told by the doctor that your liver functions are still not back to normal.
- you are suffering, or have suffered in the past, from liver tumors.
- you are suffering from hepatitis C and taking medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir and sofosbuvir/velpatasvir/voxilaprevir (see also section “Drug interactions”).

If you are suffering from one of the above-mentioned conditions, stop treatment and tell the doctor. The doctor will tell you about other contraceptive methods that may be more suitable for you.

Special warnings regarding use of the medicine

- Before you start taking Microgynon 30, read the information later in this section regarding blood clots. It is especially important to read about the symptoms of a blood clot listed in section 2 “Blood clots”.
- It is important that you understand the advantages and disadvantages of taking oral contraceptive pills before beginning to use, or to decide whether to continue taking them. Although oral contraceptive pills suit most healthy women, they do not suit everyone. Tell the doctor if you are suffering from medical conditions or risk factors mentioned in this leaflet.
- If you have to undergo a blood test, inform the doctor that you are taking an oral contraceptive pill, since combined oral contraceptive pills can affect the results of certain tests.

When should you contact the doctor?

Urgently seek medical attention

- if you notice possible signs of a blood clot that may indicate the formation in your body of a blood clot in the leg (i.e., deep vein thrombosis), a blood clot in the lungs (i.e., pulmonary embolism), a heart attack or a stroke (see “Blood clots” in section 2).

For a description of the symptoms of these serious side effects, please see “How to recognize a blood clot” in section 2.

- Some of the conditions listed below may worsen when taking oral contraceptive pills, or can indicate that Microgynon 30 is not suitable for you. You may be able to use Microgynon 30, but closer monitoring by your doctor will be necessary.

Before using Microgynon 30, inform your doctor if any of the following conditions applies to you, develops or worsens while taking Microgynon 30.

- 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 Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- If you have systemic lupus erythematosus (lupus – a disease that affects your immune system)
- If you have hemolytic uremic syndrome (a blood clotting disorder causing failure of the kidneys)
- If you have sickle cell anemia (an inherited disease of the red blood cells)

- If you are suffering from an inflammation of the pancreas (pancreatitis)
- If you suffer from elevated levels of fat in the blood (hypertriglyceridemia) or if you have a family history of this condition. Hypertriglyceridemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas)
- If you need to undergo a surgery, or you are immobile for a long time (see “Blood clots” in section 2)
- If you have recently given birth, you are at an increased risk of blood clots. Consult your doctor regarding how soon after delivery you can start taking Microgynon 30
- If you are suffering from an inflammation in the veins under the skin (superficial thrombophlebitis)

- If you suffer from varicose veins
- If you have diabetes
- If you or a close relative have ever suffered from heart problems, or blood circulation problems such as high blood pressure
- If you or a close relative have ever suffered from blood clotting problems
- If you suffer from an inherited disease called porphyria
- If you are overweight (obese)
- If you suffer from migraines
- If you have any illness that worsened during pregnancy or on previous use of oral contraceptive pills (see section 4 “Side effects”)

Blood clots

Using a combined hormonal contraceptive, such as Microgynon 30, 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 be developed:

- in the veins (a condition referred to as a “venous thrombosis”, “venous thromboembolism” or VTE)
- in the arteries (a condition 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, life-threatening conditions may arise.

It is important to remember that the overall risk of a harmful blood clot due to use of Microgynon 30 is small.

How to recognize a blood clot

Seek urgent medical attention if you notice any of the following signs or symptoms.

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none">● swelling of one of the legs or along a vein in the leg or foot, especially when accompanied by:<ul style="list-style-type: none">○ pain or tenderness in the leg which may only be felt when standing or walking○ increased warmth in the affected leg○ change in color of the skin on the leg, e.g., turning pale, red or blue	Deep vein thrombosis

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none">● sudden unexplained breathlessness or rapid breathing● sudden cough without an obvious cause, which may bring up blood● sharp chest pain which increases with deep breathing● severe lightheadedness or dizziness● rapid or irregular heartbeat	Pulmonary embolism

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none">● severe stomach pain <p>If you are unsure, talk to the doctor, as some of these symptoms, such as coughing or shortness of breath, may be mistaken for a milder condition such as a respiratory tract infection (e.g., a common cold).</p>	Pulmonary embolism

Are you experiencing any of these signs?	What are you possibly suffering from?
Symptoms that most commonly occur in one eye: <ul style="list-style-type: none"> ● sudden loss of vision or ● painless blurring of vision which can progress to loss of vision 	Retinal vein thrombosis (blood clot in the eye)
<ul style="list-style-type: none"> ● chest pain, discomfort, pressure or heaviness ● sensation of squeezing or fullness in the chest, arm or below the breastbone ● feeling of fullness, choking or indigestion 	Heart attack

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none"> ● 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 heartbeat 	Heart attack
<ul style="list-style-type: none"> ● sudden weakness or numbness of the face, arm or leg, especially on one side of the body ● sudden confusion, trouble speaking or understanding 	Stroke

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none">● 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	Stroke

Are you experiencing any of these signs?	What are you possibly suffering from?
<p>Sometimes, the symptoms of stroke can be brief, with an almost immediate and full recovery, but you must still seek urgent medical attention as you may be at risk of another stroke.</p>	<p>Stroke</p>
<ul style="list-style-type: none"> ● swelling and slight blue discoloration of the extremities ● severe stomach pain 	<p>Blood clots blocking other blood vessels</p>

If you are suffering from one of these conditions, refer to the doctor immediately. Stop taking Microgynon 30 until you receive other instructions from the doctor. In the meantime, use another contraceptive method, such as a condom.

Blood clots in a vein

What can happen if a blood clot forms in a vein?

- The use of combined hormonal contraceptives has been associated with an increased risk of blood clots in the vein (venous thrombosis). However, these side effects are rare and primarily 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 may cause a deep vein thrombosis (DVT).

- If a blood clot travels from the leg and reaches the lung, it can cause a pulmonary embolism.
- Rarely, a blood 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. In addition, the risk may be higher if you resume 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 declines, but will always be slightly higher than if you were not using a combined hormonal contraceptive.

When you stop using Microgynon 30, your risk of developing a blood clot returns to its normal level within a few weeks.

What is the risk of developing a blood clot?

The risk depends on your natural risk of developing venous thromboembolism (VTE) and on the type of combined hormonal contraceptive you are taking.

The overall risk of developing a blood clot in the leg or lung (DVT or PE) with Microgynon 30 is small.

- Out of 10,000 women who are not using a 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 Microgynon 30, about 5-7 will develop a blood clot in a year.
- The risk of developing a blood clot will vary according to your personal medical history (see “Factors that increase your risk of developing a blood clot in a vein” in section 2).

	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 Microgynon 30	About 5-7 out of 10,000 women

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

The risk of developing a blood clot with Microgynon 30 is small but some conditions will increase the risk. Your risk is higher:

- if you are very overweight (body mass index or BMI over 30 kg/m²)
- if someone from 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 50). In such a case you may have an inherited blood clotting disorder
- if you have to undergo a surgery, or if you are immobile for a long time because of an injury or illness, or if your leg is in a cast. You may have to stop using Microgynon 30 at least 4 weeks before surgery or during the period when you are less mobile. If you have to stop using

- Microgynon 30, ask your doctor when you can start using it again
- with age (particularly over the age of about 35 years)
 - if you have given birth within the past few weeks

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

Air travel (for over 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 the doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that you should stop taking Microgynon 30.

If any of the above conditions change while you are using Microgynon 30, for example, if a

close family member experiences a thrombosis from an unknown cause, or if you gain a lot of weight, tell the 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 blood clot in an artery can cause serious problems. For example, a blood clot in an artery can cause a heart attack or a stroke.

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

It is important to note that the risk of a heart attack or stroke due to use of Microgynon 30 is very low but can increase:

- with age (over the age of about 35 years)
- if you smoke. When using a combined hormonal contraceptive like Microgynon 30, it is recommended that you stop smoking. If you are unable to stop smoking and you are more than 35 years old, your doctor may advise you to use a different type of contraceptive
- if you are overweight
- if you suffer from high blood pressure
- if there has been a case of a heart attack or stroke at a young age (less than about 50) in your immediate family. In such a case, you could also have a higher risk of having a heart attack or stroke
- if you, or one of your immediate family members, suffers from high blood fat levels (cholesterol or triglycerides)

- if you suffer from migraines, especially “migraines with aura”
- if you have a heart function problem (a heart valve disorder, a disturbance of heart 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 even higher.

If any of the above conditions changes while using Microgynon 30, for example, if you start smoking, a close family member experiences a thrombosis from an unknown cause, or you gain a lot of weight, tell your doctor.

Oral contraceptive pills and cancer

While high-dosage oral contraceptive pills reduce the risk of developing cancer of the ovaries and womb in long-term use, it is not clear whether low dosage contraceptive pills, such as Microgynon 30, will also provide the same protective effect. However, it also seems that taking contraceptive pills slightly increases the risk of developing cancer of the cervix – although the reason for this may be more due to having sex without a condom than due to use of contraceptive pills. All women should routinely have a cervical smear test performed.

If you are suffering, or have suffered in the past, from breast cancer, use of oral contraceptive pills is not recommended. The pills slightly increase your risk of breast cancer. The risk increases

with longer periods of taking oral contraceptive pills, but returns to normal within about 10 years of stopping its use. Since breast cancer is rare in women under the age of 40, the extra cases of breast cancer diagnosed in current and recent oral contraceptive pill users is small. For example:

- Out of 10,000 women who have never taken oral contraceptive pills, about 16 will have breast cancer by the time they are 35 years old.
- Out of 10,000 women who took oral contraceptive pills for 5 years in their early twenties, about 17–18 will have breast cancer by the time they are 35 years old.
- Out of 10,000 women who have never taken oral contraceptive pills, about 100 will have breast cancer by the time they are 45 years old.

- Out of 10,000 women who took oral contraceptive pills for 5 years in their early thirties, about 110 will have breast cancer by the time they are 45 years old.

Your risk of breast cancer increases:

- if you have a close relative (mother, sister or grandmother) who has had breast cancer.
- if you are severely overweight.

Refer to a doctor immediately if you notice changes in your breasts, such as dimpling of the skin, changes in the nipple or if you notice or feel any lumps.

Taking oral contraceptive pills has also been linked with liver diseases, such as jaundice and noncancerous liver tumors, but these cases are rare. In rarer cases, oral contraceptive pills have

been linked with some forms of liver cancer in women who have taken the medicine for a long time.

Refer to a doctor immediately if you experience severe stomach pain, or yellowing of the skin or whites of the eye (jaundice). You may need to stop using Microgynon 30.

Psychiatric disorders

Some women using hormonal contraceptives, including Microgynon 30, have reported depression or depressed mood. Depression may be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and symptoms of depression, contact your doctor for further medical advice as soon as possible.

Smoking

It is recommended to stop smoking when using a combined hormonal contraceptive such as Microgynon 30. If you are unable to stop smoking and you are over the age of 35 years, your doctor may recommend that you use a different type of contraceptive method.

Tests and follow-up

- Before starting use of an oral contraceptive pill, the doctor will ask you about your and your family's medical history, will check your blood pressure and will rule out the possibility that you are pregnant. Additional tests, such as a breast examination, may be necessary, but only if you need to have these tests performed or if you have specific concerns.

- Routine checkups at your doctor should be performed during the course of treatment, including a cervical smear test.
 - Every month, check if there have been changes in your breasts and nipples; tell the doctor if you notice or feel any change, such as lumps or dimples in the skin.
 - If you have to perform blood tests, tell your doctor, as the pills can affect the results of certain tests.
- Before a surgery, make sure that the doctor knows you are taking Microgynon 30. You may be asked to stop taking the medicine at least 4 weeks before the surgery. This is to lower the risk of a blood clot (see “Blood clots” in section 2). The doctor will tell you when you can resume taking the medicine.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is particularly important to inform the doctor or pharmacist if you are taking any of the following medicines that can influence the levels of Microgynon 30 in the blood, thereby impairing its effectiveness:

- medicines used to treat epilepsy, such as barbiturates, primidone, phenytoin, carbamazepine, oxcarbazepine, topiramate
- certain medicines used to treat AIDS (HIV) and hepatitis C infection (called protease inhibitors and non-nucleoside reverse transcriptase inhibitors), such as ritonavir, nelfinavir, nevirapine
- griseofulvin to treat fungal infections

- CYP3A4 enzyme inhibitors, such as itraconazole, voriconazole and fluconazole (used to treat fungal infections) and antibiotics of the macrolide group (such as erythromycin) that may increase the levels of estrogen and/or progestogen in the blood
- certain antibiotics to treat infectious diseases, such as rifampicin
- St. John's Wort (*Hypericum*) to treat depressive moods
- etoricoxib (anti-inflammatory and painkiller)
- medicines whose blood concentrations may be increased when used with Microgynon 30 - cyclosporine, tizanidine, theophylline
- medicines whose blood concentrations may be reduced when used with Microgynon 30 - lamotrigine

If you are taking one of the above-mentioned medicines, Microgynon 30 may not be suitable for you and you will need to use an extra contraceptive method for a while. The doctor will tell you if this is necessary and for how long.

In addition, it is recommended that you check the leaflets of the medicines you are taking to see if they can be used concomitantly with hormonal contraceptives.

Furthermore, Microgynon 30 may affect the activity of other medicines. Your doctor may adjust the dosage of the medicines you are taking concomitantly with to Microgynon 30.

Do not use Microgynon 30 if you are suffering from hepatitis C and taking medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir, and sofosbuvir/

velpatasvir/voxilaprevir, as these products may lead to an increase in the results of liver function blood tests (increase in the liver enzyme ALT). Your doctor will prescribe for you another type of contraceptive prior to starting treatment with these medicinal products. You can resume the use of Microgynon 30 about 2 weeks after completing treatment with these products. See section 2 “Do not use the medicine if”.

Use of the medicine and food

The medicine can be swallowed on an empty stomach or with food.

Pregnancy, breastfeeding and fertility

Do not take Microgynon 30 if you are pregnant.

If you think you may be pregnant, do a pregnancy test before you stop taking the medicine.

Use of Microgynon 30 while breastfeeding may lead to a reduction in the volume of milk produced and change its composition. Tiny quantities of the active substances are secreted in breast milk. These quantities may affect the baby, especially during the first 6 weeks after birth. If you are breastfeeding, your doctor may advise you not to take Microgynon 30. He will be able to help you choose an alternative contraceptive method. Breastfeeding does not prevent you from getting pregnant.

Driving and use of machines

Microgynon 30 has no effect on the ability to drive and operate machines.

Important information regarding some of the ingredients of the medicine

Microgynon 30 contains lactose and sucrose. If you have been told by a doctor that you have an intolerance to certain sugars, consult the doctor before commencing treatment with Microgynon 30.

3) HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about your dose or about how you should use this medicine.

- The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally one tablet per day, at a set time, for 21 days. After taking the tablets for 21 days, take a 7-day break.

Do not exceed the recommended dose

- Mode of administration

Swallow the tablet whole, with water, if necessary.

Do not crush/halve/chew so as not to damage the tablet coating.

- Duration of treatment

Take Microgynon 30 every day for 21 days

Each Microgynon 30 strip has 21 tablets. The day of the week and an arrow pointing you in the direction of progression are marked on the strip, on the back of each tablet. Start by taking the

tablet marked with the correct day of the week; continue taking the tablets in the direction of the arrows. Take one tablet every day until you have finished the strip.

Take a 7-day break

After 21 days of taking the tablets, take a 7-day break. So, if you took the last tablet of the strip on a Friday, take the first tablet of the next strip on the Saturday of the following week. Within a few days of taking the last tablet, you will have menstrual bleeding. The bleeding may still not have stopped by the time you start a new strip of pills. There is no need for an extra contraceptive method during the 7-day break – as long as you have taken the tablets as per the instructions and started the next strip on time.

Start a new strip

Start a new strip – even if the menstrual bleeding hasn't stopped yet. Always start the new strip on time.

As long as you use Microgynon 30 as per the instructions, you will always start a new strip on the same day of the week.

- Starting use of Microgynon 30

Taking Microgynon 30 for the first time or after discontinued use

It is recommended to take the first tablet on the first day of your period. In this way, you will have contraceptive protection starting from the first tablet.

Switching to Microgynon 30 from another oral contraceptive pill

- **if you are taking a 21-day pill:** Start taking Microgynon 30 the next day after you finish the other oral contraceptive pill. This way, you will have contraceptive protection starting from the first tablet. Menstrual bleeding will only occur after finishing the Microgynon 30 strip.
- **if you are taking a 28-day pill:** Start taking Microgynon 30 the day after taking the last active tablet from the other strip. This way, you will have contraceptive protection starting from the first tablet. Menstrual bleeding will only occur after you finish the Microgynon 30 strip.
- **or if you are taking a progestogen-only pill (POP):** Start taking Microgynon 30 on the first day of menstrual bleeding, even if you have already taken the progestogen-only pill on that day. This way, you will have contraceptive protection immediately.

Starting Microgynon 30 after a miscarriage or abortion

If you have had a miscarriage or an abortion **within the first three months of pregnancy**, your doctor may tell you to start taking Microgynon 30 immediately. This way, you will have contraceptive protection starting from the first tablet.

If you have had a miscarriage or an abortion **after the third month** of pregnancy, consult the doctor. You may need to use an extra contraceptive method, such as a condom, for a short time.

Using contraceptives after giving birth

If you have just gave birth, the doctor will advise you to take Microgynon 30 21 days after delivery, provided that you are fully mobile. There is no need to wait for a menstrual bleeding. You must use another method of contraception, such as a condom, until you start taking

Microgynon 30 and for the first 7 days of use.

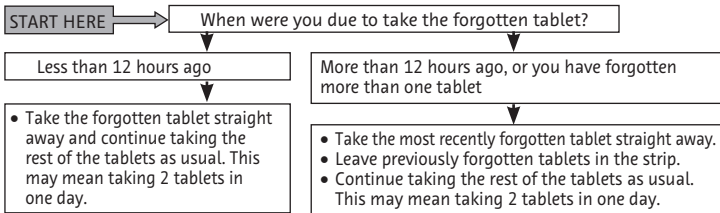
If you accidentally took a higher dosage

It is unlikely that taking more than one tablet will cause harm, but you may feel nauseous, vomit or have vaginal bleeding. Such bleeding may also appear in girls who have not yet had their first menstrual period and have accidentally taken the medicine. Consult the doctor if you experience any of these symptoms.

If you took an overdose, or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take a tablet, follow the following instructions:



The chart continued on next page

- Do not worry, your contraceptive protection should not be reduced.

- Use an additional contraceptive method (e.g., condom) for the next 7 days.
- Check how many tablets are left until the end of the strip after taking the most recently forgotten tablet.

7 or more tablets left in the strip

Fewer than 7 tablets left in the strip

- Do not forget to use an extra contraceptive method for the next 7 days.

- Do not forget to use an extra contraceptive method for the next 7 days.

The chart continued on next page

- When you have finished the strip, start a 7-day break before starting a new strip.
- **If you have forgotten one or more tablets from the first week of the strip (days 1-7), and you had sex in that week, you could become pregnant.**
Contact your doctor or pharmacist for advice as soon as possible. They may recommend that you use emergency contraception.

- When you have finished the strip, start a new strip immediately, without a break.
- If you do not have menstrual bleeding after you have finished the second strip, do a pregnancy test before starting another strip.
- **If you have forgotten one or more tablets from the first week of the strip (days 1-7), and you had sex in that week, you could become pregnant.**
Contact your doctor or pharmacist for advice as soon as possible. They may recommend that you use emergency contraception.

If you forgot to take any tablet from the strip, and menstrual bleeding does not occur during the pill-free break, you may be pregnant. Contact the doctor as soon as possible, or perform a home pregnancy test.

If you started a new strip late, or you extended the break beyond 7 days, you may not be protected from pregnancy. If you had sex in the last 7 days, consult the doctor. You may need emergency contraception. In addition, you should use an extra contraceptive method, such as a condom, for the next 7 days.

If you lost a tablet

Choose one of the following two options:

Take the last tablet of the strip in place of the lost one. Continue taking all the other tablets as usual, on their designated days. Your cycle will be one day shorter than normal, but the contraceptive protection will not be affected. After the 7-day break, the day for starting a strip will change and will be one day earlier than the previous strip.

Or, if you have another strip and you do not want to change the starting day of your cycle, take a tablet from the spare strip. Continue taking the rest of the tablets from your current strip as usual. You can then keep the opened strip as a spare strip, in case you lose any more tablets.

In the event of vomiting or diarrhea

If you suffer from vomiting or severe diarrhea within 4 hours of taking the tablet, there is no guarantee that the daily tablet will be fully absorbed from the digestive system.

If you get better within 12 hours of taking Microgynon 30, follow the instructions in this section “If you lost a tablet”, which explains how you should take another tablet.

If you suffer from vomiting or diarrhea for more than 12 hours after taking a tablet, follow the instructions in this section “If you forgot to take the medicine”.

Tell the doctor if the digestive disturbances carry on or get worse. He may recommend another method of contraception.

A missed period – is there a chance you are pregnant?

Occasionally, you may not have menstrual bleeding. This could mean that you are pregnant, but it is very unlikely if you have taken the tablets as per the instructions. Start the next strip at the designated time. If you think there is a chance you are pregnant (for example, if you missed a tablet or if you took other medicines concomitantly), or if you miss a second menstrual bleed, you should do a home pregnancy test. If you are pregnant, stop taking Microgynon 30 and refer to a doctor.

When you want to get pregnant

If you are planning to become pregnant, it is recommended to use another method of contraception after stopping Microgynon 30 until you get your period. Your doctor will rely

on the date of your natural period to predict the estimated birth due date. However, it will not cause you or your baby any harm if you become pregnant straight away.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult your doctor or pharmacist.

4) SIDE EFFECTS

As with any medicine, use of Microgynon 30 may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

If you have one or more of the side effects, especially if it is severe or prolonged, or if there is a change in your health that you think can be related to Microgynon 30, inform your doctor.

An increased risk of blood clots in the veins (venous thromboembolism [VTE]) or blood clots in the arteries (arterial thromboembolism [ATE]) exists in all women taking combined hormonal contraceptives. For more detailed information on the different risks arising from use of combined hormonal contraceptives, see section 2 “Before using the medicine”.

Serious side effects – refer to a doctor immediately

Rare side effects – effects that occur in 1-10 in 10,000 users

- harmful blood clots in a vein or artery for example:
 - in a leg or foot (deep vein thrombosis)
 - in a lung (pulmonary embolism)
 - heart attack
 - stroke
 - mini-stroke or temporary stroke-like symptoms, known as a transient ischemic attack (TIA)
 - blood clots in the liver, stomach/intestine, kidneys or eyes

The risk of developing a blood clot may be higher if you have any other factor that increases

this risk (for more information on the risk factors and blood clot symptoms, see section 2 “Before using the medicine”).

- Signs of a blood clot (see “Blood clots” in section 2).

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 section 2 under “Before using Microgynon 30, inform your doctor if...”)**.

- Signs of a severe allergic reaction:
 - swelling of the hands, face, lips, mouth, tongue or throat. Swelling of the tongue or throat may lead to difficulty swallowing and breathing

- a red raised rash (urticaria) and itching
- Signs of breast cancer include:
 - dimpling of the skin
 - changes in the nipple
 - lumps you see or feel
- Signs of cancer of the cervix include:
 - vaginal discharge that smells and/or contains blood
 - unusual vaginal bleeding
 - pelvic pain
 - painful sexual intercourse

- Signs of severe liver problems include:
 - severe pain in the upper abdomen
 - yellowing of the skin or eyes (jaundice)
 - inflammation of the liver (hepatitis)
 - itching all over the body

If you have any of the above-mentioned effects, refer to a doctor immediately. The doctor may instruct you to stop taking Microgynon 30.

Additional, less serious side effects

Common side effects – effects that occur in 100-1000 in 10,000 users

- nausea

- stomach ache
- weight gain
- headache
- mood swings or depressive mood
- sore or tender breasts

Uncommon side effects – effects that occur in 10-100 in 10,000 users

- vomiting and stomach upset
- fluid retention
- migraine
- reduced libido

- breast enlargement
- rash, which may be itchy

Rare side effects – effects that occur in 1-10 in 10,000 users

- intolerance to contact lenses
- weight loss
- increased libido
- vaginal or breast discharge

Other reported side effects

- During the first few months, intermenstrual bleeding (spotting or light bleeding) may occur. This intermenstrual bleeding will usually stop once your body has adjusted to the medicine. If the

- bleeding is heavy, prolonged or resumes, refer to a doctor (see “Breakthrough bleeding” in section 4).
- Chloasma (yellowish-brown patches on the skin). These patches can appear even after using Microgynon 30 for a few months. The incidence of these patches can be reduced by avoiding exposure to sunlight or ultraviolet (UV) radiation.
 - Occurrence or exacerbation of a movement disorder called chorea
 - Crohn’s disease or ulcerative colitis
 - Medical conditions that may worsen during pregnancy or with previous use of the medicine:
 - o yellowing of the skin (jaundice)
 - o persistent itching (pruritus)
 - o liver or kidney function problems

- gallstones
- certain rare medical conditions such as systemic lupus erythematosus
- blister-like rash (herpes gestationis) during pregnancy
- an inherited deafness of the otosclerosis type
- if you or someone from your family are suffering from sickle cell anemia
- swelling of parts of the body (hereditary angioedema)
- an inherited disease called porphyria
- cancer of the cervix

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, or that you suspect has been caused by the use of

Microgynon 30, consult with the doctor.

Breakthrough bleeding

Some women taking Microgynon 30 have light bleeding or spotting between periods, especially during the first few months of treatment. This bleeding will usually stop within a day or two and is nothing to worry about. Continue taking Microgynon 30 as usual. The effect will most likely disappear after using a few strips.

Breakthrough bleeding can also occur due to irregular use of Microgynon 30; therefore, be sure to take the pill at the same time every day. In addition, breakthrough bleeding can be due to use of other medicines.

Consult the doctor if you get breakthrough bleeding or spotting that:

- carries on for more than a few months
- started after you have been taking Microgynon 30 for a while
- carries on even after you've stopped taking Microgynon 30

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
<https://sideeffects.health.gov.il>

5) HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store at a temperature of up to 25°C.
- Do not discard medicines into the waste bin. Ask the pharmacist what to do with medicines you no longer need; this way, you will help protect the environment.

6) FURTHER INFORMATION

- In addition to the active ingredients, the medicine also contains:
Lactose monohydrate, sucrose, maize starch, calcium carbonate, talc, macrogol 6000, povidone 25000, titanium dioxide (E171), povidone 700000, glycerol 85%, magnesium stearate, montanglycol wax, ferric oxide pigment yellow (E172).
Each tablet contains 32.97 mg lactose monohydrate and 19.371 mg sucrose.
- What the medicine looks like and the contents of the package
Round, beige, film-coated tablets.
The tablets are provided in blister (tray) strips of 21 tablets. Each package contains 1 or 3 strips.
Each tablet is marked on the back of the blister with a day of the week.

Not all package sizes may be marketed.

- **Registration holder and address:** Bayer Israel, Ltd., 36 Hacharash St., Hod Hasharon 4527702.
- **Manufacturer and address:** Bayer A.G, Berlin, Germany
- Revised in April 2021 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 027 43 21707 00