



Microgynon®

(Levonorgestrel / ethinylestradiol)

Package leaflet: Information for the user
Microgynon
150 micrograms / 30 micrograms coated tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Keep this leaflet. You may need to read it again.
If you have any further questions, ask your doctor or pharmacist.

Important information about combined hormonal contraceptives (CHCs):
When used correctly, they are among the most reliable reversible methods of contraception.
They cause a slight increase in the risk of a blood clot in the veins and arteries, especially during the first year of use or when use of a combined hormonal contraceptive is resumed after an interval of 4 weeks or more.

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

1. WHAT MICROGYNON IS AND WHAT IT IS USED FOR

Microgynon is a contraceptive medicine (a "pill"). Each tablet contains a small amount of two different female sex hormones, i.e. levonorgestrel and ethinylestradiol.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MICROGYNON

General notes
Please read the information about blood clots in section 2 before you start using Microgynon. It is particularly important to read the information about the symptoms of a blood clot (see section 2, "Blood clots").

Before you use Microgynon, your treating doctor will ask you in detail about your medical history and that of your close relatives. The doctor will measure your blood pressure and, depending on your personal situation, will carry out further tests.

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Table with 2 columns: Are you experiencing one of these signs?, What might you be suffering from?
Signs include chest pain, dizziness, sudden weakness, etc. Conditions include Heart attack, Stroke, Blood clots blocking other blood vessels.

BLOOD CLOT IN A VEIN
What can happen if a blood clot forms in a vein?
Use of combined hormonal contraceptives has been associated with a higher risk of blood clots in a vein (venous thrombosis).

What is the greatest risk of developing a blood clot in a vein?
The risk of developing a blood clot in a vein is greatest during the first year of first-time use of a combined hormonal contraceptive.

How great is the risk of blood clot formation?
The risk depends on your natural risk for VTE and the type of combined hormonal contraceptive you are using.

- Factors increasing the risk of a blood clot in a vein
- if you are severely overweight (Body Mass Index or BMI over 30 kg/m2)
- if one of your close relatives has experienced a blood clot in the leg, lung or any other organ at a young age (i.e. below 50 years).

Table with 2 columns: Risk of blood clot formation per year
Women not using a combined hormonal preparation in the form of a pill/patch/ring and not pregnant: Around 2 out of 10,000 women

Factors increasing the risk of a blood clot in a vein
The risk of a blood clot with Microgynon is low, but is increased as a result of some diseases and risk factors. The risk is increased:
- if you are severely overweight (Body Mass Index or BMI over 30 kg/m2)
- if one of your close relatives has experienced a blood clot in the leg, lung or any other organ at a young age (i.e. below 50 years).

What can happen if a blood clot forms in an artery?
Just like a blood clot in a vein, a clot in an artery can cause serious problems. It can cause a heart attack, for example.

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Some medicines can have an effect on the blood levels of Microgynon and lead to a reduction in the contraceptive effectiveness or to unexpected bleeding. These include:
- medicines for the treatment of:
 > gastro-intestinal motility disorders (e.g. metoclopramide)
 > epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate or felbamate)
 > tuberculosis (e.g. rifampicin)
 > HIV and hepatitis C viral infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine)
 > fungal infections (griseofulvin, azole antifungals such as itraconazole, voriconazole, fluconazole)
 > bacterial infections (macrolide antibiotics, e.g. clarithromycin, erythromycin)
 > certain heart diseases, high blood pressure (calcium channel blockers, e.g. verapamil, diltiazem)
 > arthritis, osteoarthritis (etoricoxib)
 > the herbal remedy St. John's wort

Taking the pill at the same time as the antibiotic troleandomycin can increase the risk of bile accumulation.
Microgynon can influence the effectiveness of certain other medicines, e.g.
- medicines containing ciclosporin
- lamotrigine, an anti-epileptic (this could lead to an increased frequency of seizures)
- melatonin
- midazolam
- theophylline
- tizanidine

Do not use Microgynon if you have hepatitis C and are taking medicines that contain ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/sofosbuvir, because these medicines may result in elevated liver function values in blood tests (elevated ALT liver enzymes). Your doctor will recommend a different method of contraception before treatment is started with these medicines.
Microgynon can be used again approximately 2 weeks after the end of treatment. See the section «Microgynon must not be used».
Ask your doctor or pharmacist for advice before taking any medicine.

Microgynon with food and drink
Microgynon can be taken with or without food, if necessary with some water. Microgynon should not be taken together with grapefruit juice.
Laboratory tests
Hormonal contraceptives can affect the results of certain laboratory tests. So, if you need to have a blood test, tell your doctor or the laboratory staff that you are taking the pill.

Pregnancy and breast-feeding
Pregnancy
If you are pregnant, you must not take Microgynon. If you become pregnant while taking Microgynon, you must stop taking Microgynon immediately and consult your doctor. If you wish to become pregnant, you can stop Microgynon at any time (see also "If you wish to stop taking Microgynon").
Breast-feeding
Women should not use Microgynon during breast-feeding except on medical advice. Ask your doctor if you are breast-feeding and would like to take the pill.

Driving and using machines
There are no indications that taking Microgynon has any influence on the ability to drive and use machines.

Microgynon contains lactose and sucrose
For this reason, if you have been told that you have an intolerance to some sugars, please consult your doctor before taking Microgynon.

3. HOW TO TAKE MICROGYNON

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Each blister contains 21 tablets. The foil is marked with the particular day of the week when the tablet should be taken.

Take 1 Microgynon tablet daily for 21 days, if necessary together with some water. The tablets should be taken at about the same time each day. It does not matter whether you take the tablets on an empty stomach or with meals.

After you have taken all 21 tablets, do not take any tablets for the next 7 days. Your monthly period (withdrawal bleed) will start during these 7 days, usually 2-3 days after taking the last Microgynon tablet.

Start on the next blister on the eighth day, even if you are still bleeding. This means, on the one hand, that you will start the new strip always on the same day of the week and, on the other hand, that your withdrawal bleed should occur on the same days each month.

When to start on the first strip
If you have not been using any hormone-based contraceptive in the past month:
Start taking Microgynon on the first day of your cycle (i.e. on the first day of your monthly period). If you start taking Microgynon on this day (the first day of your monthly period), you will be immediately protected against pregnancy. You can also start between days 2 and 5 of your cycle, but you must then use extra contraceptive measures (e.g. a condom) during the first 7 days of tablet-taking.

If you are switching from another combined hormonal contraceptive (pill with two hormonal active substances) or a contraceptive vaginal ring or patch:
You can start taking Microgynon preferably on the day after taking the last active tablet (the last tablet containing active substances) of your previous pill or on the day after removing the vaginal ring or patch, but by no later than on the day after the tablet-free (ring- or patch-free) days of your previous product (or after taking the last active tablet of your previous product).

If you are switching from a product containing only one hormone (progesterone) (the so-called "mini-pill", an injectable, an implant or a progestogen-releasing intrauterine system ("coil")):
You can stop the "mini-pill" on any day you choose and start taking Microgynon immediately on the day after. After switching from an implant or "coil", start taking Microgynon on the day when the implant or "coil" is removed or, after an injectable, at the time when the next injection would normally be due. In all cases, you must use an extra method of contraception for the first 7 days of tablet-taking (e.g. a condom).

If you have had a miscarriage or abortion in the first three months of pregnancy:
Please talk to your doctor.

If you have just had a baby or a miscarriage after the third month of pregnancy:
Do not start taking Microgynon any earlier than 21 to 28 days after the birth or miscarriage. If you start taking it after Day 28, you must additionally use a barrier method of contraception (e.g. a condom) during the first 7 days of taking Microgynon.

If you have already had sexual intercourse after childbirth before starting to take Microgynon, you must make sure that you are not pregnant, or you must wait for your first monthly period before taking Microgynon.

If you are breast-feeding after childbirth and wish to start taking Microgynon (again):
Read the section "Breast-feeding".

If you are not sure when you can start, ask your doctor.
If you take more Microgynon than you should
There are no reports of serious harmful consequences after taking too many Microgynon tablets.

Nausea and vomiting may occur if you have taken several tablets at once or if you may experience vaginal bleeding. Even girls who have not had their first menstruation and have accidentally taken Microgynon may experience vaginal bleeding.

If you have taken too many Microgynon tablets or discover that you have accidentally swallowed some tablets, ask your doctor or pharmacist for advice.

If you forget to take Microgynon
If you are less than 12 hours late in taking any one tablet, the contraceptive effect is still assured. You must take the forgotten tablet as quickly as possible and then continue to take the next tablets at the usual time.

If you are more than 12 hours late in taking your tablet, the contraceptive effect will no longer be assured. The more tablets you have missed, the greater the risk of pregnancy.

For this reason, you should bear in mind the following rules:
- Tablet-taking should never be interrupted for more than 7 days.

The effectiveness of Microgynon is assured only after 7 days of uninterrupted tablet-taking.

If you are more than 12 hours late in taking a tablet between Days 1 and 7 (please also see the diagram):
Take the tablet as quickly as possible, even if this means having to take two tablets at the same time. Then continue taking your tablets as usual.

If you are more than 12 hours late in taking a tablet between Days 8 and 14 (please also see the diagram):
Take the tablet as quickly as possible, even if this means having to take two tablets at the same time. Then continue taking your tablets as usual.

If you are more than 12 hours late in taking a tablet between Days 15 and 21 (please also see the diagram):
The closer you are to the tablet-free interval, the greater the likelihood of pregnancy. However, pregnancy can still be prevented by adjusting the dosing schedule.

If you observe the following instructions, you need not take any extra contraceptive measures, provided you have been using the tablets correctly over the 7 days before the missed tablet. If you have not taken these tablets correctly or if you have missed more than one tablet, you should use additional contraceptive protection (e.g. a condom) during the next 7 days.

If you are more than 12 hours late in taking a tablet between Days 1 and 7 (please also see the diagram):
Take the tablet as quickly as possible, even if this means having to take two tablets at the same time. Then continue taking your tablets as usual.

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Take the tablet as quickly as possible, even if this means having to take two tablets at the same time. Then continue taking your tablets as usual.

If you are more than 12 hours late in taking a tablet between Days 15 and 21 (please also see the diagram):
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If you observe the following instructions, you need not take any extra contraceptive measures, provided you have been using the tablets correctly over the 7 days before the missed tablet. If you have not taken these tablets correctly or if you have missed more than one tablet, you should use additional contraceptive protection (e.g. a condom) during the next 7 days.

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Take the tablet as quickly as possible, even if this means having to take two tablets at the same time. Then continue taking your tablets as usual.

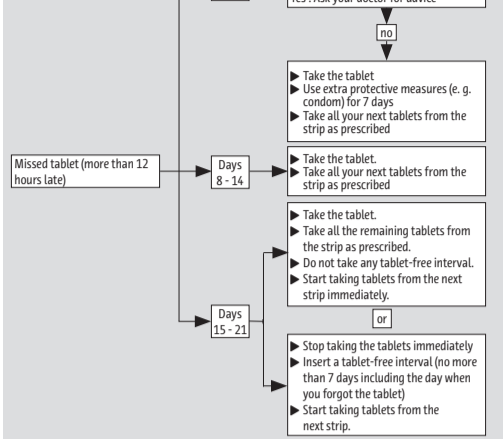
If you are more than 12 hours late in taking a tablet between Days 8 and 14 (please also see the diagram):
Take the tablet as quickly as possible, even if this means having to take two tablets at the same time. Then continue taking your tablets as usual.

If you are more than 12 hours late in taking a tablet between Days 15 and 21 (please also see the diagram):
The closer you are to the tablet-free interval, the greater the likelihood of pregnancy. However, pregnancy can still be prevented by adjusting the dosing schedule.

opt for the first of the two following possibilities only and use extra contraceptive protection during the next 7 days.

- 1. Take the tablet as quickly as possible, even if this means having to take two tablets at the same time. Then continue taking your next tablets at the usual time. Instead of observing a subsequent 7-day tablet-free interval, start on the next strip straight away. Most probably, you will not experience withdrawal bleeding until the end of the second strip. However, you may experience mild or menstruation-like bleeding whilst on the second strip.
2. You can also stop taking the tablets and immediately start the 7-day tablet-free interval, which should also include the day when the tablet was forgotten, and then carry on taking tablets from a new strip.

If you have forgotten more than one tablet and no withdrawal bleeding occurs during the normal tablet-free interval, the possibility of pregnancy must be considered.



Points to consider if you suffer vomiting or severe diarrhoea
If you experience vomiting or severe diarrhoea within the first 3 to 4 hours of taking a tablet, the active substances in the pill may not have been completely absorbed by your body. This situation is like forgetting a tablet.

Delaying your period days: points to consider
Even though it is not recommended, you can delay your monthly period by leaving out the tablet-free interval and continuing with the next Microgynon strip straight away, until you have completed it. Whilst on this second strip, mild or menstruation-like bleeding may occur.

You should ask your doctor for advice before deciding to delay bleeding. Changing the day of the week when your monthly period starts: points to consider

If you want to change the day of the week when your period starts, you can shorten the tablet-free interval by as many days as you wish. The shorter the tablet-free interval, the greater the likelihood that no withdrawal bleeding will occur and that there will be mild or menstruation-like bleeding whilst you are on the next strip.

If you are not sure about what to do, ask your doctor. If you wish to stop taking Microgynon

You can stop taking Microgynon at any time. If you do not wish to become pregnant, talk to your doctor about other safe contraceptive methods. If you wish to become pregnant, stop taking Microgynon and wait until your monthly period before trying to conceive. In this way, you will be able to calculate the estimated delivery date more easily.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you get side effects, especially if they are serious and persistent, or if there is a change in your state of health and you think this is due to Microgynon, please talk to your doctor.

Serious side effects
All women using combined hormonal contraceptives are at increased risk of blood clots in the veins (venous thromboembolism [VTE]) or arteries (arterial thromboembolism [ATE]). For more details on the various risks associated with the use of combined hormonal contraceptives, see section 2 "What you need to know before you take Microgynon".

Other possible side effects that may occur when using these pills are:
Common side effects (up to 1 in 10 users may be affected)
- Mood swings, depressive moods
- Headache
- Nausea, abdominal pain
- Breast pain or sensitive breasts

Uncommon side effects (up to 1 to 100 users may be affected):
- Decreased sex drive (reduced libido)
- Migraine
- Vomiting, diarrhoea
- Skin rash
- Nettle rash (itching)
- Swollen breasts
- Fluid accumulation (fluid retention)

Rare side effects (up to 1 in 1,000 users may be affected):
- Contact lens intolerance
- Hypersensitivity
- Increased sex drive (increased libido)
- Vaginal or breast discharge
- Skin redness, blotches or lumps beneath the skin
- Weight loss
- 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 symptoms similar to a stroke, called a transient ischaemic attack (TIA)
 > blood clots in the liver, stomach/intestines, kidneys or the eye.

The likelihood of a blood clot may be increased if you suffer from other diseases that increase this risk (for more information on disorders that increase the risk of a blood clot and symptoms of a blood clot, see section 2).

The following severe side effects have been reported somewhat more frequently in women taking the pill, although it is not clear whether this increase in frequency is triggered by its use (see also section 2 "When special care is needed when taking Microgynon")

Cervical cancer, breast cancer
Increased blood pressure
Liver dysfunction, liver tumours

The following disorders have also been associated with the pill: Crohn's disease, ulcerative colitis, epilepsy, migraine, endometriosis (with symptoms of very painful monthly periods), benign warts, tumours, porphyria (a metabolic disorder causing abdominal pain and neurological disorders), systemic lupus erythematosus (when the body's own organs and tissues are attacked and damaged by the immune system), herpes in late pregnancy, chorea minor (Sydenham's chorea; rapid, involuntary twitching or jerking movements), haemolytic-uraemic syndrome (a disorder that occurs following E. coli-induced diarrhoea), liver problems manifesting as jaundice, metabolic disorders, a form of hearing loss (otosclerosis).

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.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

To report any side effect(s):
Egypt:
Egyptian Pharmaceutical Vigilance Centre
Hotline: 15301
Email: pv.followup@edaegypt.gov.eg
Website: www.edaegypt.gov.eg

Jordan:
Tel: +962-6-5632000
JFDA email: jpc@jfdaj.o
JFDA website: www.jfdaj.o
http://primaryreporting.jo-umc.org/JO

Oman:
+968-2444 1999
Fax: +968-24602287
Email: pharma-vigi@omh.gov.om
Website: www.moh.gov.om

Other Countries:
Please contact the relevant competent authority

5. HOW TO STORE MICROGYNON

Keep this medicine out of the sight and reach of children. Store below 30°C. Do not use this medicine after the expiry date which is stated on the carton and strip after «Expiry date» or «EXP». The expiry date refers to the last day of that month.

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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Microgynon contains:
The active substances are: ethinylestradiol and levonorgestrel. Each coated tablet contains 30 micrograms of ethinylestradiol and 150 micrograms of levonorgestrel.

The other ingredients are: Tablet core: lactose monohydrate (see also section 2: Microgynon contains lactose and sucrose), maize starch, povidone K25, talc (E553b), magnesium stearate (Ph.Eur.) (vegetable) (E470b), Coating: sucrose (see also section 2: Microgynon contains lactose and sucrose), povidone K90, macrogol 6,000, calcium carbonate, talc, glycerol 85%, montan glycol wax, titanium dioxide (E171), yellow iron oxide (E172).

What Microgynon looks like and contents of the pack:
Microgynon tablets are beige-coloured, round, coated tablets. Microgynon is available in packs of 1, 3 and 6 blisters, each with 21 tablets. Not all pack sizes may be marketed.

Manufacturer:
Bayer Weimar GmbH and Co. KG
99427 Weimar, Germany.

Marketing authorisation holder
Bayer AG,
Kaiser-Wilhelm-Allee 1
51368 Leverkusen, Germany.
This leaflet was last revised in October 2022.

This is a medication
A medication is a product which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicines.

The doctor and the pharmacist are experts in medicine, its benefits and risks. Do not by yourself interrupt the period of treatment prescribed. Do not repeat the same prescription without consulting your doctor.

Keep medication out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

