

This is a medicament

- ▶ A medicament 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 medicament.
- ▶ 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 medicament out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

PACKAGE LEAFLET: INFORMATION FOR THE USER
Microgynon
150 micrograms / 30 micrograms coated tablets
Levonorgestrel / ethinylestradiol

Read all of this leaflet carefully before you start taking this medicine.

- ▶ Keep this leaflet. You may need to read it again.
- ▶ If you have any further questions, ask your doctor or pharmacist.
- ▶ This medicine has been prescribed for you. Do not pass it on to others. It may harm them.
- ▶ If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Microgynon is and what it is used for
2. Before you take Microgynon
3. How to take Microgynon
4. Possible side effects
5. How to store Microgynon
6. Further 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.
- ▶ Pills containing two hormones are called combined pills. Microgynon is also called a low-dose pill, as it contains only a small amount of hormones.

2. BEFORE YOU TAKE MICROGYNON

General comments

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.

This leaflet describes various cases in which you should stop Microgynon or the reliability of Microgynon may be reduced. In these cases, you should either not have sexual intercourse or use other, non-hormonal methods of contraception, e.g. a condom or another barrier method. However, do not use the calendar or temperature method. These methods may fail because Microgynon alters the monthly fluctuations in body temperature and cervical mucus.

Like all hormonal contraceptives, Microgynon offers no protection against HIV infection (AIDS) or other sexually transmitted diseases.

Do not take Microgynon:

- ▶ if you have a past or present history of blood clots in a blood vessel in your leg (thrombosis), lung (pulmonary embolism) or in other organs if you have a past or present history of disorders that may be precursors of a future heart attack (e.g. angina pectoris, which causes severe chest pain) or stroke (e.g. temporary mild stroke without permanent damage) in the presence of a disorder that increases the risk of blood clots within the arteries. This applies to the following disorders:
 - ▷ diabetes mellitus with damaged blood vessels
 - ▷ very high blood pressure
 - ▷ very high blood fat (lipid) levels (cholesterol or triglycerides)
- ▶ if you have blood coagulation problems (e.g. protein C deficiency)
- ▶ if you have a past or present history of certain forms of migraine (with so-called focal neurological symptoms)
- ▶ if you have a past or present history of inflammation of the pancreas, if accompanied by a severe metabolic disorder
- ▶ if you have a past or present history of severe liver disorders, unless your liver counts have returned to normal
- ▶ if you have a past or present history of liver tumours
- ▶ if you have a past or present history of breast cancer or genital cancer, or suspicion thereof
- ▶ if you have any unexplained vaginal bleeding
- ▶ if you are missing your monthly period, possibly due to diet or physical activity
- ▶ if you are allergic (hypersensitive) to ethinylestradiol, levonorgestrel or any of the other ingredients of Microgynon. This may cause itching, rash or swelling.

Take special care with Microgynon

In some situations, special care is needed when taking Microgynon or other combined pills and regular check-ups by your doctor may be necessary. If any of the following cases applies to you, you must tell your doctor before starting to take Microgynon. You must also consult your doctor if any of the following conditions occurs or gets worse while taking Microgynon:

- ▶ if a close relative has, or has ever had, breast cancer
- ▶ if you are known to have a liver or gallbladder disease
- ▶ if you suffer from diabetes mellitus
- ▶ if you suffer from depression
- ▶ if you suffer from Crohn's disease or any other chronic inflammatory bowel disease (ulcerative colitis)
- ▶ if you are known to have a blood disorder called HUS (haemolytic-uraemic syndrome), which causes kidney damage
- ▶ if you suffer from epilepsy (see "Taking other medicines")
- ▶ if you suffer from an immune system disease called SLE (systemic lupus erythematosus), which triggers skin changes all over the body
- ▶ if you are suffering from a type of anaemia called sickle cell anaemia if you have ever experienced a disorder that occurred for the first time during pregnancy or previous use of sex hormones, e.g. hardness of hearing, a blood disease called porphyria, a blister-type rash during pregnancy (herpes gestationis), a nerve disorder where sudden, involuntary body movements occur (Sydenham's chorea)
- ▶ if you have a past or present history of yellowish-brown pigment patches (chloasma), also known as the "mask of pregnancy", mainly on the face. In this case, it is advisable to avoid exposure to direct sunlight or ultraviolet light.
- ▶ if you suffer from hereditary angioedema (sudden swelling of the skin, mucous membranes, internal organs or brain): medicines containing oestrogens can trigger or worsen the condition. You should consult your doctor immediately if you notice symptoms of angioedema, such as swelling of the face, tongue and/or throat and/or swallowing difficulties or skin rash together with breathing problems.

Microgynon and venous/arterial blood clots

The use of any combined pill, including Microgynon, increases a woman's risk of developing a **venous blood clot (venous thrombosis)** compared with women not taking a contraceptive pill.

The risk of venous thrombosis in users of a combined pill rises:

- ▶ with increasing age
- ▶ if you are overweight
- ▶ if a close family member has ever experienced a blood clot in the leg, lung (pulmonary embolism) or any other organ at an early age if you need to have an operation, if you have had an accident or if you have been immobilised for a prolonged period of time. It is important to tell your doctor in advance that you are taking Microgynon, as you will usually need to stop taking it. Your doctor will tell you when you can start taking Microgynon again, normally about 2 weeks after you can walk again.

The likelihood of getting a blood clot is increased by taking the pill. In 100,000 women not using a pill and not pregnant, a blood clot may occur in about 5 - 10 women within one year.

In 100,000 women using a pill, e.g. Microgynon, a blood clot may occur in about 20 women within one year. The exact number is not known.

In 100,000 women who are pregnant, a blood clot may occur in about 60 women within one year.

A blood clot in the veins can get into the lung and block blood vessels (known as pulmonary embolism). The formation of a blood clot in the veins can be fatal in 1 - 2% of cases.

The level of risk of getting a blood clot can vary depending on the type of pill. Please discuss the available options with your doctor.

Use of the combined pill is also associated with an increased risk of an **arterial blood clot (arterial thrombosis)**, e.g. in the blood vessels of the heart (heart attack) or brain (stroke).

The risk of an arterial blood clot in users of a combined pill rises:

- ▶ with increasing age
- ▶ if you smoke. **You are strongly advised to stop smoking if you take Microgynon, especially if you are over 35 years of age.**
- ▶ if you have high cholesterol or triglyceride levels in your blood
- ▶ if you have high blood pressure
- ▶ if you suffer from migraine
- ▶ if you have problems with your heart (heart valve defect, heart rhythm disorder)

Stop taking Microgynon immediately and consult your doctor at once if you notice possible signs of a blood clot, e.g.:

- ▶ severe pain and/or swelling in one of your legs
- ▶ sudden severe chest pain, possibly radiating into the left arm
- ▶ sudden shortness of breath
- ▶ sudden cough with no clear cause
- ▶ unusual, severe or persistent headache or worsening of migraine
- ▶ partial or complete loss of vision or double vision
- ▶ slurred speech or problems in speaking
- ▶ dizziness or fainting
- ▶ weakness, strange feeling or numbness in a part of the body
- ▶ difficulties in controlling your movements
- ▶ sudden severe abdominal pain

Microgynon and cancer

- ▶ Cervical cancer has been observed somewhat more frequently in long-term users than in non-users of oral contraceptives; however, it is not clear to what extent differences in sexual behaviour or other factors such as the human papillomavirus (HPV) play a role.
- ▶ Breast cancer is observed somewhat more frequently in women taking combined pills, but it is not known whether this is caused by the treatment. The incidence of breast tumours decreases after discontinuation of hormonal combined pills. It is important that you examine your breasts regularly. If you feel any lumps, you must consult your doctor.
- ▶ In rare cases, benign (non-cancerous) liver tumours and, rarer still, malignant (cancerous) liver tumours have been found in users of combined pills. Consult your doctor if you experience unusually severe abdominal pain.

Bleeding between periods

When using Microgynon, unexpected bleeding (bleeding outside the tablet-free interval) may occur within the first few months. If this bleeding continues to occur after more than 3 months or if it starts again after a few months, your doctor must determine the cause.

Points to consider if there is no bleeding during the tablet-free interval

If you have taken all your tablets correctly, have not had vomiting or severe diarrhoea and have not taken any other medicines, pregnancy is very unlikely.

However, if bleeding is absent for two cycles in a row, you may be pregnant. You should then contact your doctor immediately, as pregnancy must be excluded before you take any further pills. Do not start a new blister strip until you are sure that you are not pregnant.

Taking other medicines

Always tell your doctor about which medicines or herbal products you are already using or have recently used, including medicines obtained without a prescription. Also, tell any other doctor or dentist prescribing you other medicines (or the pharmacist) that you are taking Microgynon. They can tell you whether you need to take extra contraceptive precautions (e.g. condoms) and, if so, for how long.

Some medicines can lead to a reduction in the contraceptive effectiveness of Microgynon or to unexpected bleeding. These include:

- ▶ medicines for the treatment of:
 - ▷ gastrointestinal motility disorders (e.g. metoclopramide)
 - ▷ epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate or felbamate)
 - ▷ tuberculosis (e.g. rifampicin)
 - ▷ HIV infections (ritonavir, nevirapine) or other infections (antibiotics such as griseofulvin, penicillin, tetracycline)
- ▶ 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 antiepileptic (this could lead to an increased frequency of seizures)

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

Taking Microgynon with food and drink

Microgynon can be taken with or without food, if necessary with some water.

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

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").

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

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.

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

Driving and using machines

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

Important information about some of the ingredients of Microgynon

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

Each blister contains 21 tablets. The foil is marked with the particular day of the week when the tablet should be taken. For example, if you are to start taking the tablets on a Tuesday, push the tablet through the aluminium foil marked "TUE". Take the tablets in the sequence indicated by the arrows.

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. Young girls may experience vaginal bleeding.

If you have taken too many Microgynon tablets or discover that a child has 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):**

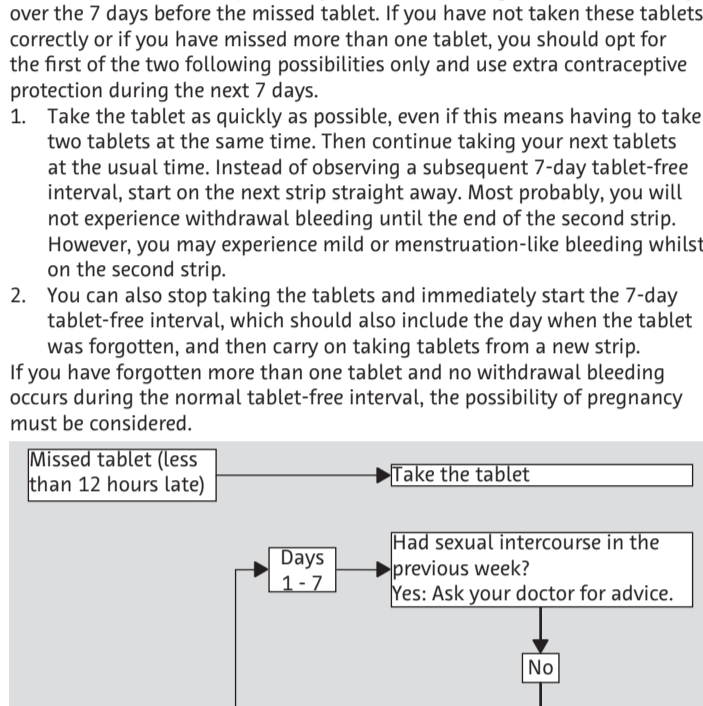
Take the tablet as quickly as possible, even if this means having to take two tablets at the same time. Then continue taking your tablets as usual. However, you must additionally use a contraceptive barrier method, e.g. a condom, for the next 7 days. If you have had sexual intercourse in the week prior to forgetting the tablet, the possibility of pregnancy must be considered. The more tablets you have missed and the nearer this has occurred to the tablet-free interval, the greater the risk of pregnancy. In this case, tell your doctor.

- ▶ **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. Provided you have taken the tablets correctly over the 7 days before the missed tablet, you need not take any extra protective measures. However, if you have not taken these tablets correctly or if more than one tablet has been missed, you must 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 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.



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. After vomiting or diarrhoea, you must take a tablet from another strip as quickly as possible; if possible, within 12 hours of when you usually take the pill. If this is not possible or more than 12 hours have passed, follow the instructions in the section "If you forget to take Microgynon".

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. As soon as you have completed this second strip, you must observe a 7-day tablet-free interval. *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. However, never lengthen the tablet-free interval. *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, Microgynon can cause side effects, although not everybody gets them.

The use of pills containing the same active substances as Microgynon is most commonly associated with side effects of headache, spotting and bleeding between periods.

Other possible side effects that may occur when using these pills are:

Common side effects (more than 1 in 100 users may be affected):

- ▶ Mood swings, depressive moods
- ▶ Headache
- ▶ Nausea, abdominal pain
- ▶ Breast pain or sensitive breasts
- ▶ Weight gain

Uncommon side effects (1 to 10 in 1,000 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 (less than 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

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 "Take special care with Microgynon")

- ▶ Venous or arterial blood clot
- ▶ 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 womb 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).

In women with inherited sudden swelling of the skin, mucous membranes, internal organs or brain (hereditary angioedema), the oestrogens in the pill can trigger or worsen the symptoms of angioedema.

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.

5. HOW TO STORE MICROGYNON

Keep out of the reach and sight of children.

Do not store above 30°C.

Do not use Microgynon 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 to protect the environment.

6. FURTHER 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: "Important information about some of the ingredients of Microgynon"), maize starch, povidone K25, talc (E553b), magnesium stearate (Ph.Eur.) [vegetable] (E470b)
 - ▷ Coating: sucrose (see also section 2: "Important information about some of the ingredients of Microgynon"), povidone 700,000, macrogol 6,000, calcium carbonate, 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.

Manufacturer

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