

MICROGYNON® 50 ED

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using MICROGYNON® 50 ED?

MICROGYNON® 50 ED contains the active ingredients ethinylestradiol and levonorgestrel. MICROGYNON® 50 ED is used to prevent pregnancy. For more information, see Section [1. Why am I using MICROGYNON® 50 ED?](#) in the full CMI.

2. What should I know before I use MICROGYNON® 50 ED?

Do not use if you have ever had an allergic reaction to MICROGYNON® 50 ED or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use MICROGYNON® 50 ED?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MICROGYNON® 50 ED and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use MICROGYNON® 50 ED?

- Take one tablet daily at about the same time every day.
- You must take MICROGYNON® 50 ED every day regardless of how often you have sex.
- Swallow the tablet whole with a full glass of water. It does not matter if you take it before or after food.

More instructions can be found in Section [4. How do I use MICROGYNON® 50 ED?](#) in the full CMI.

5. What should I know while using MICROGYNON® 50 ED?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using MICROGYNON® 50 ED.• If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.• Have regular check-ups with your doctor. When you are taking the Pill, your doctor will tell you to return for regular check-ups, including getting a Cervical Screening Test. |
| Things you should not do | <ul style="list-style-type: none">• Do not take MICROGYNON® 50 ED to treat any other conditions, unless your doctor tells you to.• Do not give your medicine to anyone else.• Do not stop taking your medicine or change the dosage without checking with your doctor. You may become pregnant if you are not using any other contraceptive and you stop taking MICROGYNON® 50 ED, or do not take a tablet every day. |
| Looking after your medicine | <ul style="list-style-type: none">• Keep your tablets in the blister pack until it is time to take them.• Keep your tablets in a cool dry place where the temperature stays below 30°C. |

For more information, see Section [5. What should I know while using MICROGYNON® 50 ED?](#) in the full CMI.

6. Are there any side effects?

Common side effects: acne; nausea; stomach pain; changes in weight; headache, including migraines; mood changes, including depression; breast tenderness or pain; hair loss or hair growth.

Serious side effects: Blood clots, jaundice (yellowing skin or yellowing eyes), you cough up blood, unexplained vaginal bleeding and breast lumps.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

MICROGYNON® 50 ED (My-crow-GUY-non 50 Ee-Dee)

Active ingredient(s): *ethinylestradiol and levonorgestrel*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MICROGYNON® 50 ED. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MICROGYNON® 50 ED.**

Where to find information in this leaflet:

- [1. Why am I using MICROGYNON® 50 ED?](#)
- [2. What should I know before I use MICROGYNON® 50 ED?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use MICROGYNON® 50 ED?](#)
- [5. What should I know while using MICROGYNON® 50 ED?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using MICROGYNON® 50 ED?

MICROGYNON® 50 ED contains the active ingredient ethinylestradiol and levonorgestrel. MICROGYNON® 50 ED is a combined oral contraceptive, commonly known as a 'birth control pill' or 'the Pill'.

MICROGYNON® 50 ED is used to prevent pregnancy.

You may also experience the following benefits:

- more regular and lighter periods – potentially resulting in a decrease in anaemia (iron deficiency)
- a decrease in period pain.

Some conditions such as pelvic inflammatory disease, ovarian cysts, ectopic pregnancy (where the foetus is carried outside of your womb), lumpy breasts, acne and cancer of the uterus (womb) and ovaries may be less common in women taking the Pill.

When taken correctly, MICROGYNON® 50 ED prevents you from becoming pregnant in several ways, including:

- inhibiting ovulation (egg release)
- changing the cervical mucus consistency, making it more difficult for the sperm to reach the egg
- changing the lining of the uterus, making it less suitable for implantation.

When the Pill is taken by women under close observation in clinical trials, it is more than 99% effective in preventing pregnancy. However, in real life the Pill is around 92% effective. This is because pills might have been missed, may have been taken with medicines that interfere with

their effectiveness, or may not be absorbed due to vomiting or diarrhoea.

Like all oral contraceptives, MICROGYNON® 50 ED is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted infections.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I use MICROGYNON® 50 ED?

Warnings

Do not use MICROGYNON® 50 ED if:

- you are allergic to ethinylestradiol or levonorgestrel, or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.
- **you have or have had a blood clot in:**
 - the blood vessels of the legs (deep vein thrombosis - DVT)
 - the lungs (pulmonary embolism - PE)
 - the heart (heart attack)
 - the brain (stroke)
 - other parts of the body.
- **you have or are concerned about an increased risk of blood clots.** Blood clots are rare. Very occasionally blood clots may cause serious permanent disability, and may even be fatal.
You are more at risk of having a blood clot when you take the Pill. However, the risk of having a blood clot when taking the Pill is less than the risk of having a blood clot during pregnancy.
- **you are concerned about an increased risk of blood clots because of age or smoking.**
The risk of having a heart attack or stroke increases as you get older. It also increases if you smoke. You should stop smoking when taking the Pill, especially if you are older than 35 years of age.
- **you are taking any antiviral medicines which contain glecaprevir, pibrentasvir, sofosbuvir, velpatasvir, voxilaprevir, ombitasvir, paritaprevir and/or dasabuvir.**
These antiviral medicines are used to treat chronic (long-term) hepatitis C (an infectious disease that affects the liver, caused by the hepatitis C virus (HCV)).
- you have, or have had any blood clotting disorders such as Protein C deficiency, Protein S deficiency,

Leiden Factor V mutation, Antithrombin III deficiency or other inherited blood clotting conditions.

- you have, or have had a confirmed blood test showing:
 - increased levels of homocysteine
 - antiphospholipid antibodies (APLAs) e.g. anticardiolipin-antibodies and lupus anticoagulant. These may increase your risk for blood clots or pregnancy losses (miscarriage).
- you have, or have had major surgery after which you have not been able to move around for a period of time.
- you have, or have had angina (chest pain).
- you have, or have had a mini-stroke (also known as TIA or transient ischaemic attack).
- you have, or have had a migraine, where you have also had problems with seeing, speaking or had or weakness or numbness in any part of your body.
- you have, or have had high risk of blood clots due to conditions such as diabetes with blood vessel damage, severe high blood pressure or severe high or low level of fats in your blood.
- you have, or have had pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood.
- you have, or have had severe liver disease and your liver function has not returned to normal.
- you have, or have had cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs).
- you have, or have had a benign or malignant liver tumour.
- you have, or have had unexplained vaginal bleeding.

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 (barrier) methods of contraception (such as condoms or a diaphragm).

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- smoke
- or anyone in your immediate family has had blood clots in the legs (DVT), or lungs (PE), a heart attack, a stroke, breast cancer or high cholesterol
- have, or have had diabetes
- have, or have had high blood pressure
- have, or have had heart valve disorders or certain heart rhythm disorders
- have, or have had migraine
- have, or have had cancer
- have, or have had hyperhomocysteinaemia, a condition characterised by high levels of the amino acid homocysteine in the blood.
- have, or have had high or low level of fats in your blood
- are overweight
- have any hereditary or acquired conditions that may make it more likely for you to get blood clots
- have high cholesterol or triglycerides

- have liver disease
- have gall bladder disease
- have jaundice (yellowing of the skin) and/or pruritus (itching of the skin) related to cholestasis (condition in which the flow of bile from the liver stops or slows)
- have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- have systemic lupus erythematosus (SLE – a disease affecting the skin all over the body)
- have haemolytic uraemic syndrome (HUS – a disorder of blood coagulation causing failure of the kidneys)
- have sickle cell disease
- have a condition that occurred for the first time, or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, a metabolic disease called porphyria, a skin disease called herpes gestationis, a neurological disease called Sydenham's chorea)
- have chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face) – if so, avoid exposure to the sun or ultraviolet radiation
- have hereditary angioedema – you should see your doctor immediately if you experience symptoms of angioedema, such as swollen face, tongue and/or pharynx and/or difficulty swallowing, or hives together with difficulty in breathing.
- you have an intolerance to some sugars.
MICROGYNON® 50 ED contains lactose.

If any of the above conditions appear for the first time, recur or worsen while taking MICROGYNON® 50 ED, you should tell your doctor.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant or think you might be pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. MICROGYNON® 50 ED is generally not recommended if you are breastfeeding.

Children under 18 years old

Do not give this medicine to a child.

- MICROGYNON® 50 ED is not intended for use in females whose periods have not yet started.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with MICROGYNON® 50 ED and affect how it works.

- medicines used to treat tuberculosis such as rifampicin, rifabutin

- a class of antibiotics known as macrolides, such as clarithromycin, erythromycin
- medicines used to treat fungal infections, such as ketoconazole, griseofulvin
- medicines used to treat HIV, such as ritonavir, nevirapine
- some medicines used to treat HCV, such as boceprevir, telaprevir, glecaprevir, pibrentasvir, ombitasvir, paritaprevir, dasabuvir
- medicines used to treat epilepsy such as phenytoin, primidone, barbiturates (e.g. phenobarbitone), carbamazepine, oxcarbazepine, topiramate, felbamate, lamotrigine
- ciclosporin, an immunosuppressant medicine
- etoricoxib, a medicine used to treat painful joint disease
- melatonin, a hormone used as a sleep aid
- midazolam, a medicine used as a sedative
- theophylline, a medicine used to treat respiratory disease
- tizanidine, a medicine used as a muscle relaxant
- some medicines used to treat high blood pressure, chest pain or irregular heartbeats such as diltiazem, verapamil
- herbal medicines containing St John's Wort
- grapefruit juice

These medicines may be affected by MICROGYNON® 50 ED, or may affect how well it works. Your doctor may need to alter the dose of your medicine, or prescribe a different medicine.

You may need to use additional barrier methods of contraception (such as condoms or a diaphragm) while you are taking any of these medicines with MICROGYNON® 50 ED and for some time after stopping them. Your doctor will be able to tell you how long you will need to use additional contraceptive methods.

Your doctor and pharmacist have more information on medicines that you need to be careful with or avoid while taking this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MICROGYNON® 50 ED.

4. How do I use MICROGYNON® 50 ED?

How much to take / use

- Take one tablet daily at about the same time every day. You must take MICROGYNON® 50 ED every day regardless of how often you have sex. This will also help you remember when to take it.
- **Swallow the tablet whole with a full glass of water.** It does not matter if you take it before or after food.
- Each blister pack is marked with the day of the week. Take your first tablet from the red area on the blister pack corresponding to the day of the week.
- **Follow the direction of the arrows on the blister pack until all the tablets have been taken.**

- A period should begin 2 to 3 days after starting to take the white inactive tablets (last row) and may not have finished before the next pack is started.
- **Always start a new blister pack on the same day of the week as your previous pack.**
- Follow the instructions provided and use MICROGYNON® 50 ED until your doctor tells you to stop.

When to take / use MICROGYNON® 50 ED

Taking MICROGYNON® 50 ED for the first time

- If you are starting MICROGYNON® 50 ED after a natural cycle, and you have not used a hormonal contraceptive in the past month, start on the first day of your period, i.e. the first day of menstrual bleeding.
- **You must also use additional barrier contraceptive precautions (e.g. condoms or a cap or diaphragm with spermicide) for the first 14 days of tablet-taking when having intercourse.**
- Your doctor will advise you when to start if you:
 - are taking MICROGYNON® 50 ED after having a baby
 - have had a miscarriage or an abortion.

Changing from a combined oral contraceptive

- Start taking MICROGYNON® 50 ED on the day after taking the last active tablet in your previous Pill pack. Bleeding may not occur until the end of the first pack of MICROGYNON® 50 ED.
- If you are not sure which were the active/inactive tablets in your previous Pill pack, ask your doctor or pharmacist. Your previous Pill pack may have different colour tablets to those of MICROGYNON® 50 ED.

Changing from a vaginal ring

Start taking MICROGYNON® 50 ED on the day of removal of the ring but at the latest when the next application would have been due.

Changing from a progestogen-only pill ('mini-pill')

- Stop taking the mini-pill on any day and start taking MICROGYNON® 50 ED at the same time the day after your last mini-pill.
- **You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 7 days of tablet-taking when having intercourse.**

Changing from a progestogen-only injection, implant or intrauterine system (IUS)

- Start taking MICROGYNON® 50 ED when your next injection is due, or on the day that your implant or IUS is removed.
- **You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 14 days of tablet-taking when having intercourse.**

Stopping MICROGYNON® 50 ED

You can stop taking MICROGYNON® 50 ED at any time. If you are considering becoming pregnant, it is recommended that you begin taking a vitamin supplement containing folic acid. It is best that you start taking folic acid tablets before you stop taking MICROGYNON® 50 ED and not stop until your doctor advises this. Ask your doctor or pharmacist about suitable supplements. It is both safe and recommended that you take folic acid during pregnancy.

Additional contraceptive precautions

When additional contraceptive precautions are required you should either abstain from sex, or use a barrier method of contraception, a cap (or diaphragm) plus spermicide, or a condom. Rhythm methods are not advised as the Pill disrupts the cyclical changes associated with the natural menstrual cycle e.g. changes in temperature and cervical mucus.

If you forget to use MICROGYNON® 50 ED

MICROGYNON® 50 ED should be used regularly at the same time each day. If you miss your dose at the usual time, and take the missed tablet within 12 hours of missing it, you should still be protected against pregnancy.

If you are more than 12 hours late, follow these detailed instructions:

For MICROGYNON® 50 ED to be most effective, ochre active tablets need to be taken uninterrupted for 7 days.

If you have been taking the ochre active tablets for 7 uninterrupted days and miss an ochre active tablet, take the missed tablet as soon as you remember, then go back to taking your Pill as you would normally, even if this means taking two tablets in one day, at the same time. You should still be protected against pregnancy.

The chance of pregnancy after missing an ochre active tablet depends on when you missed the tablet. There is a higher risk of becoming pregnant if you miss a tablet at the beginning or end of a pack.

If after taking your missed tablet you have less than 7 days of ochre active tablets left in a row, you should finish the active tablets in your pack but skip the white inactive tablets. Start taking the ochre active tablets in your next pack corresponding to the correct day of the week.

This is the best way to maintain contraceptive protection. However, you may not have a period until the end of the ochre active tablets of the second pack. You may have spotting or breakthrough bleeding on tablet-taking days.

If you have been taking the ochre active tablets for less than 7 days and miss an ochre active tablet, take the missed tablet as soon as you remember, then go back to taking your Pill as you would normally, even if this means

taking two tablets in one day, at the same time. In addition, you must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the next 7 days.

If you have had sexual intercourse in the preceding 7 days, there is a possibility of pregnancy and you may need emergency contraception. You should discuss this with your doctor or pharmacist.

If you forget to take more than one ochre active tablet, seek advice from your doctor or pharmacist about what to do.

If you have had sexual intercourse in the week before missing your tablets, there is a possibility of becoming pregnant.

If you miss a large white inactive tablet, you do not need to take them later because they do not contain any active ingredients. However, it is important that you discard the missed white tablet(s) to make sure that the number of days between taking active tablets is not increased as this would increase the risk of pregnancy. Continue with the next tablet at the usual time.

Please see the table at the end of this leaflet, ["Summary of advice if you missed an ochre active tablet more than 12 hours ago"](#).

Ask your doctor or pharmacist to answer any questions you may have.

If you use too much MICROGYNON® 50 ED

If you think that you have used too much MICROGYNON® 50 ED, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using MICROGYNON® 50 ED?

Things you should do

- If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.
- Have regular check-ups with your doctor. When you are taking the Pill, your doctor will tell you to return for regular check-ups, including getting a Cervical Screening Test. Your doctor will advise how often you need a Cervical Screening Test. A Cervical Screening

Test can detect abnormal cells lining the cervix.
Sometimes abnormal cells can progress to cancer.

- **If you are about to start on any new medicine, remind your doctor and pharmacist that you are taking MICROGYNON® 50 ED.**

Stop taking this medicine and call your doctor straight away if you notice:

- one-sided swelling of the leg and/or foot or along a vein in the leg
- pain or tenderness in the leg which may be felt only when standing or walking
- increased warmth in the affected leg; red or discoloured skin on the leg
- sudden onset of unexplained shortness of breath or rapid breathing
- sudden coughing or coughing up of blood
- sharp chest pain or sudden severe pain in the chest which may increase with deep breathing
- severe light headedness or dizziness
- rapid or irregular heartbeat
- sudden pain, swelling and slight blue discoloration of an extremity
- sudden numbness or weakness of the face, arm or leg, especially on one side of the body
- sudden trouble walking, dizziness, loss of balance or coordination
- sudden confusion, slurred speech or aphasia; sudden partial or complete loss of vision, double vision, painless blurring of vision which can progress to loss of vision
- sudden, severe or prolonged headache with no known cause
- loss of consciousness or fainting with or without seizure
- pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the chest arm, or below the breastbone
- discomfort radiating to the back, jaw, throat, arm, stomach
- feeling of being full, having indigestion or choking
- sweating, nausea, vomiting
- extreme weakness and anxiety

Remind any doctor, dentist or pharmacist you visit that you are using MICROGYNON® 50 ED.

Surgery and prolonged immobilisation

If you are going to have surgery, tell the surgeon or anaesthetist beforehand that you are taking MICROGYNON® 50 ED.

The risk of having blood clots is temporarily increased as a result of major surgery, any surgery to the legs or pelvis, neurosurgery or major trauma. In women who take MICROGYNON® 50 ED, the risk may be higher.

In women at risk of prolonged immobilisation (including major surgery, any surgery to the legs or pelvis, neurosurgery, or major trauma), your doctor may tell you to stop taking (in the case of elective surgery at least four weeks in advance) and not resume until two weeks after

complete remobilisation. Another method of contraception should be used to avoid unintentional pregnancy. Your doctor may prescribe other treatment (e.g. treatment for blood clots) if MICROGYNON® 50 ED has not been discontinued in advance.

Temporary immobilisation

Other risk factors for blood clotting include temporary immobilisation including air travel of greater than 4 hours, particularly in women with other risk factors. **Consult your doctor if you plan to air travel for greater than 4 hours.**

High blood pressure

Consult your doctor if you develop high blood pressure while taking MICROGYNON® 50 ED – you may be told to stop taking it.

Pregnancy

If you become pregnant while taking this medicine, tell your doctor immediately.

Vomiting

If you vomit within 3 to 4 hours, or have severe diarrhoea after taking an ochre active tablet, the active ingredients may not have been completely absorbed.

This is like missing a tablet. Follow the advice for missed tablets.

Unexpected bleeding

If you have unexpected bleeding and it continues, becomes heavy, or occurs again, tell your doctor.

When taking this Pill for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary products, but continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to the Pill, usually after about 3 months.

Period

If you have missed a period, but you have taken all your tablets, it is unlikely that you are pregnant, as long as:

- you have taken the pink active tablets at the right time
- you have not been taking a medicine(s) that may interfere with your Pill
- you have not vomited or had severe diarrhoea during this cycle.

If this is so, continue to take MICROGYNON® 50 ED as usual. If you have any concerns consult your doctor or pharmacist.

If you miss your period twice in a row, you may be pregnant, even if you have taken the Pill correctly. Stop taking MICROGYNON® 50 ED and seek advice from your doctor. You must use a non-hormonal method of contraception, (such as condoms or a diaphragm) until your doctor rules out pregnancy.

Sexually transmitted infections (STIs)

MICROGYNON® 50 ED will not protect you from HIV-AIDS or any other sexually transmitted infections (STIs), such as chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, human papillomavirus and syphilis.

To protect yourself from STIs, you will need to use additional barrier contraceptives (e.g. condoms).

Things you should not do

- Do not take MICROGYNON® 50 ED to treat any other conditions, unless your doctor tells you to.
- Do not give your medicine to anyone else.
- Do not stop taking your medicine or change the dosage without checking with your doctor. You may become pregnant if you are not using any other contraceptive and you stop taking MICROGYNON® 50 ED, or do not take a tablet every day.

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them.
If you take the tablets out of the pack they may not keep well.
- Keep your tablets in a cool dry place where the temperature stays below 30°C.
- Do not take this medicine if the packaging is torn or shows signs of tampering.
If the packaging is damaged, return it to your pharmacist for disposal.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|--|--|
| Skin-related: <ul style="list-style-type: none">• acne• hair loss or hair growth Gastrointestinal-related: <ul style="list-style-type: none">• nausea• stomach pain Metabolic: <ul style="list-style-type: none">• changes in weight Neurological: <ul style="list-style-type: none">• headache, including migraines• mood changes, including depression Breast-related: <ul style="list-style-type: none">• breast tenderness or pain | Speak to your doctor if you have any of these less serious side effects and they worry you. |

Serious side effects

| Serious side effects | What to do |
|--|---|
| Blood clot-related: <ul style="list-style-type: none">• pain in the chest, arm or below the breastbone• pain or discomfort that goes to your back• breathlessness and/or difficulty breathing• swelling, pain or tenderness of one leg• sudden weakness, numbness or bad 'pins and needles' of the face, arm or leg, especially on one side of the body• sudden trouble walking, dizziness, loss of balance or coordination• severe, sudden stomach pains• a fainting attack or you collapse• unusual headaches or migraines that are worse than usual• sudden problems with speaking, seeing or understanding what people are saying to you Liver-related: <ul style="list-style-type: none">• jaundice (yellowing skin or yellowing eyes) Bleeding-related: <ul style="list-style-type: none">• you cough up blood | Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. |

Reproductive and breast-related:

- unexplained vaginal bleeding
- breast lumps

Blood clots and the Pill

Blood clots may block blood vessels in your body. This type of blood clot is also called thrombosis.

Blood clots sometimes occur in the deep veins of the legs. If a blood clot breaks away from the veins where it has formed, it may reach and block the blood vessels of the lungs, causing pulmonary embolism.

Blood clots can also occur in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke).

Blood clots are a rare occurrence and can develop whether or not you are taking the Pill. They can also happen during pregnancy. The risk of having blood clots is higher in Pill users than in non-users, but not as high as during pregnancy.

The risk of a blood clot is highest during the first year of taking the Pill for the first time, or after having a break from the Pill for 4 weeks or more.

If you notice possible signs of a blood clot, stop taking MICROGYNON® 50 ED and consult your doctor immediately. To prevent pregnancy, you must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm).

If you are concerned about an increased risk of blood clots while on MICROGYNON® 50 ED, speak to your doctor.

Cancer and the Pill

Breast cancer has been diagnosed slightly more often in women who take the Pill than in women of the same age who do not take the Pill.

This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after women stop taking the Pill. It is not known whether the difference is caused by the Pill. It may be that these women were examined more often, so that the breast cancer was noticed earlier.

It is important that you check your breasts regularly and contact your doctor if you feel any lumps.

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 has been reported to occur more often in women who have been taking the Pill for a long time. This

finding may not be caused by the Pill, but may be related to sexual behaviour and other factors.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What MICROGYNON® 50 ED contains

| Each ochre active tablet contains: | |
|---|--|
| Active ingredients (main ingredients) | <ul style="list-style-type: none"> • 50 micrograms of ethinylestradiol • 125 micrograms of levonorgestrel |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none"> • calcium carbonate • glycerol • glycol montanate • iron oxide yellow • lactose monohydrate • macrogol 6000 • magnesium stearate • maize starch • povidone • purified talc • sucrose • titanium dioxide |
| Potential allergens | Lactose monohydrate |
| Each white inactive tablet contains: | |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none"> • calcium carbonate • glycol montanate • lactose monohydrate • macrogol 6000 • magnesium stearate • maize starch • povidone • purified talc • sucrose |
| Potential allergens | Lactose monohydrate |

Do not take this medicine if you are allergic to any of these ingredients.

Tablets do not contain gluten.

Tablets also do not contain tartrazine or any other azo dyes.

What MICROGYNON® 50 ED looks like

- MICROGYNON® 50 ED active tablets are round and ochre-coloured.
- MICROGYNON® 50 ED inactive tablets are round and white-coloured.
- MICROGYNON® 50 ED comes in a box containing 1, 2, 3 or 4 blister packs (AUST R 10695).
- Not all pack sizes may be marketed.
- Each blister pack contains 21 round ochre active tablets and 7 round white inactive tablets.

Who distributes MICROGYNON® 50 ED

Bayer Australia Ltd
ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073

See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

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SUMMARY OF ADVICE IF YOU MISSED AN OCHRE ACTIVE TABLET MORE THAN 12 HOURS AGO

| | | | | |
|---|------------|--|----------|---|
| Before missing your tablet, did you take ochre active tablets for the previous 7 days? | No | Did you have sex in the 7 days before missing the tablet? | → | <p>No</p> <p>Take the tablet missed AND use extra barrier precaution for 7 days. If there are fewer than 7 ochre active tablets left in the pack, finish the ochre active tablets and go straight to the ochre active tablets of the next pack. This means you skip the white inactive tablets.</p> <p>Yes</p> <p>See your Doctor or Pharmacist for advice.</p> |
| | Yes | Does your pack still have 7 ochre active tablets in a row to follow? | → | <p>No</p> <p>Take the tablet you missed AND complete taking the ochre active tablets. Skip the white inactive tablets. Start your next pack with ochre active tablets.</p> <p>Yes</p> <p>Take the tablet you missed AND complete the pack as normal.</p> |