

PACKAGE LEAFLET: INFORMATION FOR THE USER

Micronor[®] oral contraceptive tablets

Norethisterone

Micronor is a registered trademark

Five important things to know about the Pill.

- The Pill is a reliable contraceptive and may reduce your risk of cancer of the ovary and womb if used for a long time.
- The Pill will not protect you against sexually transmitted diseases.
- This medicine can increase your risk of problems such as blood clots and breast cancer.
- Some women should not take the Pill because of current medical problems or illnesses. Please read the leaflet to make sure Micronor is right for you.
- To prevent pregnancy it is important to take Micronor as instructed and start each strip on time. Please make sure that you understand what to do if you miss a pill or think you are pregnant.

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 questions or need more advice, ask your doctor, family planning nurse 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 severe**, or if you notice any not listed in this leaflet, please tell your doctor, family planning nurse or pharmacist.

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1 What Micronor does

Micronor is a 'progestogen only' oral contraceptive pill (POP or 'mini Pill').

You take it to stop getting pregnant.

This low-dose contraceptive contains a female sex hormone called progestogen. This hormone changes the lining of the womb and so prevents an egg from growing there. Also, Micronor makes the fluid (mucus) in your cervix thicker which makes it more difficult for sperm to enter the womb.

Micronor is a 28-day Pill – you take one every day without a break.

The benefits of taking the Pill include:

- it is one of the most reliable reversible methods of contraception if used correctly
- it doesn't interrupt sex
- it usually makes your periods regular, lighter and less painful
- it may help with pre-menstrual symptoms

Micronor will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this.

Micronor needs to be taken as directed to prevent pregnancy.

2 Make sure Micronor is OK for you

It's important that you understand the benefits and risks of taking the Pill before you start taking it, or when deciding whether to carry on taking it. Although the Pill is suitable for most healthy women it isn't suitable for everyone.

→ Tell your doctor if you have any of the illnesses or risk factors mentioned in this leaflet.

Before you start taking the Pill

- Your doctor will ask about you and your family's medical problems and check your blood pressure. You may also need other checks, such as a breast examination but only if these are necessary for you or you have any special concerns.

While you're on the Pill

- You will need **regular check-ups** with your doctor or family planning nurse, usually when you need another prescription of the Pill.
- You should go for **regular cervical smear tests**.
- **Check your breasts** and nipples every month for changes – tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.
- **If you need a blood test** tell your doctor that you are taking the Pill, because the Pill can affect the results of some tests.
- **If you're going to have an operation**, make sure your doctor knows about it. You may be advised to stop taking the Pill to reduce the risk of a blood clot (see section 2.1). Your doctor will tell you when you can start taking the Pill again.

2.1 The Pill and blood clots

The Pill may slightly increase your risk of having a blood clot (called a thrombosis), especially in the first year of taking it.

A clot in a leg vein – a deep vein thrombosis (or DVT) – is not always serious. However, if it moves up the veins to the lungs, it can cause chest pain, breathlessness, collapse or even death. This is called a 'pulmonary embolism' and is very rare.

You are more at risk of having a blood clot in your veins:

- as you get **older**
- if you are **seriously overweight**
- if you **smoke**
- if you or any of your close family have had **blood clots**

- if you have any **blood clotting problem** that needs treatment with a medicine such as warfarin
- if you're **off your feet for a long time** because of major surgery, injury or illness
- if you have had one or more **miscarriages**
- if you have **recently had a baby**

→**Tell your doctor** if any of these risk factors apply to you. Taking the Pill may add to this risk so Micronor may not be suitable for you.

Signs of a blood clot include:

- **painful swelling in your leg**
- sudden **chest pain difficulty breathing**
- sudden **changes in eyesight** (such as loss of vision or blurred vision)

→**See a doctor as soon as possible. Do not take any more Micronor** until your doctor says you can. Use another method of contraception, such as condoms, in the meantime.

Very rarely, blood clots can also form in the blood vessels of the heart (causing a **heart attack**) or the brain (causing a **stroke**). In healthy young women the chance of having a heart attack or stroke is extremely small.

You are more at risk of having a heart attack or stroke:

- as you get **older**
- if you have **high blood pressure**
- if you **smoke** or **drink** too much **alcohol**
- if you **have high levels of fat** in your blood or are **seriously overweight**
- if you have an **irregular heartbeat** (atrial fibrillation), problems with heart valves **or heart failure**
- if you or someone in your close family has had a **heart attack** or **stroke** at a young age
- if you have **migraines**
- if you have **diabetes**
- if you have a blood problem called **sickle cell anaemia**.
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→**Tell your doctor** if any of these risk factors apply to you. Taking the Pill may add to this risk so Micronor may not be suitable for you.

Signs of a heart attack or stroke include:

- sudden **crushing pains in your chest** which may reach your left arm
- sudden **weakness** or **numbness** in one side or part of your body
- **severe headache** or **migraine** for the first time or worse than normal
- **slurred speech** or any other difficulties affecting your speech
- any sudden **changes to your eyesight** (such as loss of vision or blurred vision)

→**See a doctor as soon as possible. Do not take any more Micronor** until your doctor says you can. Use another method of contraception, such as condoms, in the meantime.

2.2 The Pill and cancer

The Pill reduces your risk of cancer of the ovary and womb if used for a long time. However, it also seems to slightly increase your risk of **cancer of the cervix** – although this may be due to having sex without a condom, rather than the Pill. All women should have regular **smear tests**.

If you have **breast cancer**, you should not take the Pill. The Pill slightly increases your risk of breast cancer.

Breast cancer is rare in women under the age of 40 whether or not they are on the Pill. The age you stop taking the Pill is the most important risk factor for breast cancer. There is slightly more chance of you having breast cancer the older you are when you stop taking the Pill, compared to women who have never taken the Pill.

- Of 10,000 women who have **never taken the Pill**:
 - by the age of 30, **44** women will have breast cancer
 - by the age of 40, **160** women will have breast cancer.
- Of 10,000 women who **take the Pill for up to 5 years**:
 - and then **stop** by the age of 20, there will be **less than 1 extra case** of breast cancer diagnosed in the next 10 years
 - and then **stop** by the age of 30, there will be **about 2 to 3 extra cases** of breast cancer diagnosed in the next 10 years
 - and then **stop** by the age of 40, there will be **about 10 extra cases** of breast cancer diagnosed in the next 10 years.

The risk of having breast cancer returns to normal within about 10 years of stopping the Pill.

Your risk of breast cancer is higher:

- as you get older
- if you have a close relative (mother, sister or grandmother) who has had breast cancer
- if you are seriously overweight

→ **See a doctor as soon as possible if you notice any changes in your breasts**, such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.

Taking the Pill has also been linked to **liver** diseases, such as jaundice and non-cancer liver tumours, but this is rare. Very rarely, the Pill has also been linked with some forms of liver cancer in women who have taken it for a long time.

→ **See a doctor as soon as possible if you get severe pain in your stomach, or yellow skin or eyes** (jaundice). You may need to stop taking Micronor.

2.3 Micronor should not be taken by some women

→ Tell your doctor or family planning nurse if you have any medical problems or illnesses.

Do not take Micronor if any of the following apply to you.

- If you have **breast cancer**

- If you are **allergic** (hypersensitive) to any of the ingredients in Micronor. →**If you suffer from either of these**, or get them for the first time while taking Micronor, contact your doctor as soon as possible. Do not take Micronor as it may put your health at risk..
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2.4 Micronor can make some illnesses worse

Some of the conditions listed below can be made worse by taking the Pill. Or they may mean it is less suitable for you. You may still be able to take Micronor but you need to take special care and have check-ups more often. **Tell your doctor or family planning nurse if any of these apply to you :**

If you have or have had problems with your **heart**,

- If you have had **breast cancer**
- If you have **severe liver problems**
- If you have the disease **Systemic Lupus Erythematosus (SLE)**
- If you have ever had a **stroke** (including a “mini-stroke” also known as “TIA”)
- If you have a blood problem called **porphyria**

→**Tell your doctor or family planning nurse if any of these apply to you. Also tell them if you get any of these for the first time while taking the Pill**, or if any get worse or come back, because you may need to stop taking Micronor and use another method of contraception, such as condoms.

2.5 Taking other medicines

If you ever need to take another medicine at the same time as being on the Pill, always tell your doctor, pharmacist or dentist that you're taking Micronor. Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

Some medicines can stop Micronor from working properly – for example:

- **some medicines used to treat epilepsy** (such as carbamazepine and phenytoin)
- **bosentan** (for high blood pressure in the blood vessels of the lungs)
- **rifampicin** and **rifabutin** (for the treatment of TB)
- **griseofulvin** (for fungal infections)
- **certain sedatives** (called ‘barbiturates’)
- **St. John’s Wort** (a herbal remedy)
- **anti-HIV medicines**
- **aprepitant and fosaprepitant** (for prevention of nausea and vomiting caused by certain cancer drug treatments)

If you do need to take one of these medicines, Micronor may not be suitable for you or you may need to use extra contraception for a while. Your doctor, pharmacist or dentist can tell you if this is necessary and for how long.

2.6 Taking Micronor with food and drink

There are no special instructions about food and drink while on Micronor.

2.7 Pregnancy and breast-feeding

Do not start to use Micronor if you are pregnant. If you think you might be pregnant while taking Micronor, do a pregnancy test to confirm that you are before you stop taking it. If you do get pregnant while taking this Pill, there is a slightly greater chance that it could form outside of the womb (ectopic pregnancy).

If you are breast-feeding, your doctor or family planning nurse may advise you not to take Micronor. Talk to them about alternative contraception. Breast-feeding may not stop you getting pregnant.

2.8 Driving and using machines

Micronor has no known effect on the ability to drive or use machines.

2.9 Micronor contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using Micronor.

3 Taking Micronor

3.1 How to take it

To prevent pregnancy, always take Micronor as described below. Check with your doctor or family planning nurse if you are not sure.

Take Micronor every day

Micronor comes in a strip of 28 pills, each marked with a day of the week.

- **Take your pill at the same time every day.** (Take special care when travelling between different time zones.)
- Start by taking a pill marked with the correct day of the week.
- Follow the direction of the arrows on the strip.
- Swallow each pill whole, with water if necessary. Do not chew the pill.

Starting a new strip

When you have taken all 28 pills in the strip, **start a new strip on the next day.** Do not have any pill-free days.

As long as you take Micronor correctly, you will always start each new strip on the same day of the week.

3.2 Starting Micronor

As a new user or starting the Pill again after a break

You must take your first Micronor pill up to and including day 5 of your next period. (By starting in this way, you will have contraceptive protection with your first pill.)

Changing to Micronor from another contraceptive Pill

- **If you are currently taking a 21-day Pill**, start Micronor the next day after the end of the strip. You will have contraceptive protection with your first pill.
- **If you are taking a 28-day Pill**, start taking Micronor the day after your last active pill. You will have contraceptive protection with your first pill.

- **If you are taking another progestogen-only Pill (POP or 'mini Pill')**, start Micronor the next day after the end of the previous strip. You will have contraceptive cover straight away.

Changing to Micronor from a contraceptive implant

- Start taking Micronor the same day the implant is removed. You will have contraceptive protection with your first pill.

Changing to Micronor from a contraceptive injection

- Start taking Micronor on, or before, the day the repeat injection is due. You will have contraceptive protection with your first pill.

Changing to Micronor from a coil

- Either start taking Micronor 2 days before the coil is removed. You will have contraceptive protection with your first pill.
- Or, if you start taking Micronor the same day as removal of the coil, if possible you must use extra contraception, such as condoms, for 7 days before removal and until you have taken the first 2 pills correctly.

Starting Micronor after a miscarriage or abortion

If you have had a miscarriage or an abortion, your doctor may tell you to start taking Micronor straight away. This means that you will have contraceptive protection with your first pill.

If you start more than 1 day after a miscarriage or abortion, use extra precautions (for instance condoms) for the next 2 days.

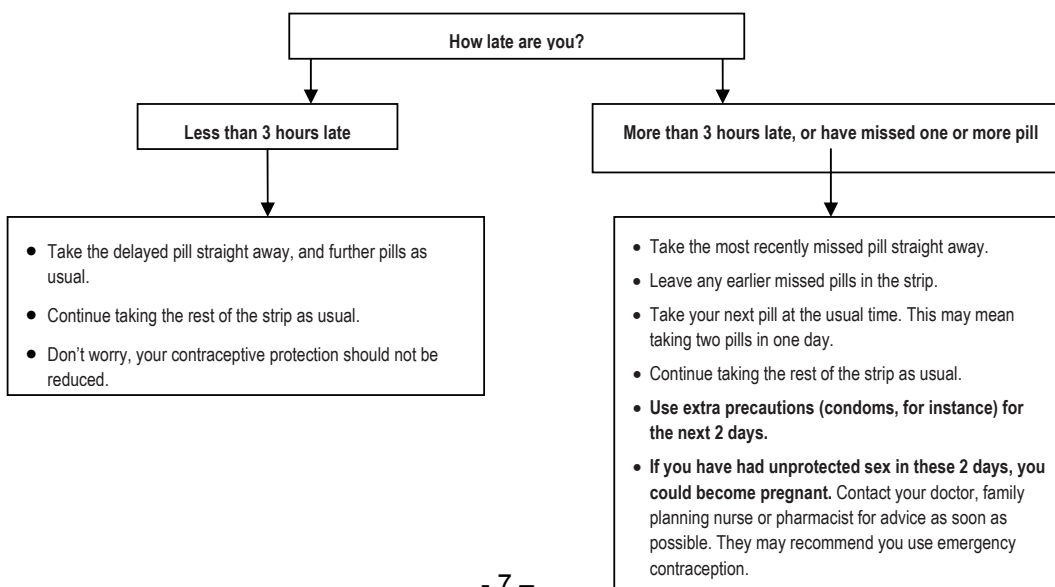
Contraception after having a baby

Start taking Micronor straight away after your baby is born. This means that you will have contraceptive protection with your first Pill.

If you start later than this, use extra precautions (for instance condoms) for the next 2 days.

Ask your doctor for advice about contraception.

3.3 A missed pill



If you have missed any of the pills in a strip, and you do not bleed within 45 days of your last period, you may be pregnant. Stop taking Micronor and contact your doctor or family planning clinic, or do a pregnancy test yourself.

3.4 A lost pill

If you lose a pill, just take a pill from a spare strip. Then take all the other pills from your current strip as usual. You can then keep the opened spare strip in case you lose any more pills.

3.5 If you are sick or have diarrhoea

If you are sick or have very bad diarrhoea, your body may not get its usual dose of hormones from that pill.

If you have been sick **within 3 hours of taking Micronor**, just take a pill from a spare strip. Carry on taking your pills as normal if you can. You won't need to use extra contraception.

If you have been sick **more than 3 hours after taking Micronor** carry on taking your pills as normal and use extra contraception for 2 days after you are better.

→**Talk to your doctor if your stomach upset carries on or gets worse.** He or she may recommend another form of contraception.

3.6 Missed a period – could you be pregnant?

Occasionally, you may miss a period. This could mean that you are pregnant, but that is very unlikely if you have taken your pills correctly. Start your next strip at the normal time. If you think that you might have put yourself at risk of pregnancy (for example, by missing pills or taking other medicines), or if you miss a second bleed, you should do a pregnancy test. You can buy these from the chemist or get a free test at your family planning clinic or doctor's surgery. If you are pregnant, stop taking Micronor and see your doctor.

3.7 Taking more than one pill should not cause harm

It is unlikely that taking more than one pill will do you any harm, but you may feel sick, vomit or have some vaginal bleeding. Talk to your doctor if you have any of these symptoms.

3.8 When you want to get pregnant

If you are planning a baby, it's best to use another method of contraception after stopping Micronor until you have regular periods. Your doctor or midwife relies on the date of your last natural period to tell you when your baby is due. However, it will not cause you or the baby any harm if you get pregnant straight away.

4 Possible side effects

Like all medicines, Micronor can cause side effects, although not everybody gets them.

→**Tell your doctor, pharmacist or family planning nurse** if you are worried about any side effects which you think may be due to Micronor.

4.1 Serious side effects –see a doctor straight away

Signs of a blood clot in a vein include:

- **painful swelling in your leg**
- sudden **chest pain, difficulty breathing**
- sudden **changes in eyesight** (such as loss of vision or blurred vision).

Signs of heart attack or stroke include:

- a **severe headache or migraine** for the first time, or any that is worse than normal
- sudden **changes in eyesight** (such as loss of vision or blurred vision)
- sudden **weakness or numbness** in one side or part of your body
- **slurred speech** or any other difficulties affecting your speech
- sudden **crushing pains in your chest** which may reach your left arm.

Signs of breast cancer include:

- **dimpling** of the skin
- **changes in the nipple**
- any **lumps** you can see or feel.

Signs of severe liver problems include:

- severe **pain** in your **upper abdomen**
- **yellow skin or eyes** (jaundice).

Other serious side effects include:

- **hives (urticaria), swelling** of the face, lips, mouth, tongue or throat which may cause **difficulty in swallowing or breathing**. These may be signs of **severe allergy**
- **severe** bleeding from the vagina
- **severe pain in the lower abdomen, bleeding or collapse** (may be signs of pregnancy outside the womb)

→**If you think you may have any of these, see a doctor straight away.**

You may need to stop taking Micronor.

4.2 Other possible side effects – tell your doctor

Very common side effects (affects more than 1 in 10 patients)

- **Bleeding and spotting between your periods**

Common side effects (affects more than 1 in 100 patients)

- **Headache**, (but if severe, unusual or long lasting, see a doctor as soon as possible)
- Feeling **dizzy**

- Feeling **sick or being sick**
- **No menstrual periods**
- **Tender breasts**
- Feeling **tired**
- **Weight gain.**

Uncommon side effects (affects fewer than 1 in 100 patients)

- **Depression; feeling nervous**
- **Stomach pain and other stomach problems**
- **Acne**
- **Rash**
- **Hair thinning** (alopecia), **excessive hair growth**
- **Pain in legs**
- **Painful periods with heavy bleeding**
- **Vaginal discharge**
- **Ovarian cyst** (may cause pain and swelling of the abdomen, changes in periods)

Rare side effects (affects fewer than 1 in 1000 patients)

- **Hypersensitivity (allergic reaction)**

Frequency not known

- **Itchy rash**
- **Breast problems** such as painful breasts; reduced amount of breast milk (if breast feeding)
- **Irregular periods**
- **Bleeding when stopping Micronor**

→ **Tell your doctor, pharmacist or family planning nurse** if you are worried about any side effects which you think may be due to Micronor. Also tell them if any existing conditions get worse while you are taking Micronor.

4.3 Bleeding between periods should not last long

A few women have a little unexpected bleeding or spotting while they are taking Micronor, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking Micronor as usual. The problem should disappear after the first few strips.

You may also have unexpected bleeding if you are not taking your pills regularly, so try to take your pill at the same time every day. Also, unexpected bleeding can sometimes be caused by other medicines.

→ **Make an appointment to see your doctor** if you get breakthrough bleeding or spotting that:

- carries on for more than the first few months
- starts after you've been taking Micronor for a while
- carries on even after you've stopped taking Micronor.

5 How to store Micronor

Keep all medicines out of the reach and sight of children.

Store Micronor below 25°C. Store it in the original package to protect it from light.

Do not use Micronor after the expiry date shown on the strip. The expiry date refers to the last day of that month.

Do not throw away any medicines down a drain or into a bin. Ask your pharmacist what to do with any medicines you do not want. This will help to protect the environment.

6 What is in Micronor and who makes it

What is in Micronor

Each box of Micronor contains three strips each containing 28 tablets.

The tablets are round and white, and engraved 'C035'.

Each tablet contains 350 micrograms norethisterone.

Micronor also contains the inactive ingredients: lactose (a type of sugar), magnesium stearate and pregelatinised starch.

The company that holds the product licence for Micronor:

Janssen-Cilag Ltd, 50-100 Holmers Farm Way, High Wycombe,
Buckinghamshire HP12 4EG, UK

Micronor is made by:

Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium

OR

McGregor Cory Ltd, Middleton Close, Banbury, Oxfordshire OX16 4RS, UK

**For information in large print, tape, CD or Braille, telephone
0800 7318450.**

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