

PATIENT INFORMATION LEAFLET

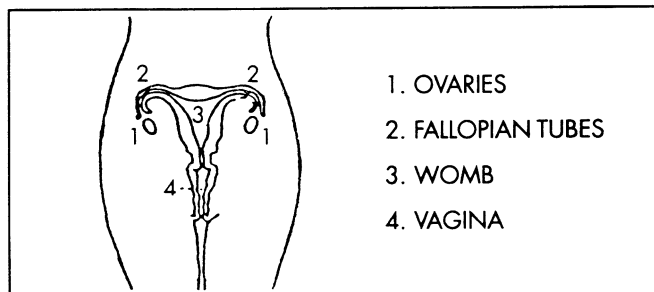
MICRONOR® Oral Contraceptive Tablets (norethisterone)

WHY SHOULD YOU READ THIS LEAFLET?

Please read this leaflet carefully before you use MICRONOR®. It tells you what you should know to be able to use this product correctly. This leaflet does not contain the complete information about this medicine. If you have any questions about what is written here or wish for any further information, please ask your doctor or pharmacist.

HOW DOES YOUR BODY GET READY FOR PREGNANCY?

- You are able to become pregnant throughout your fertile years, that is to say, from the time when you start to have menstrual periods until you reach an age when your periods stop (usually your late 40s).
- The time between the beginning of one menstrual period and the next is called the menstrual cycle. It lasts about 28 days. In the middle of the menstrual cycle one of the ovaries releases an egg into a Fallopian tube (see picture); this is called ovulation. The egg moves down the Fallopian tube towards the womb. The egg will then either be:



- Fertilised by one sperm – Discarded with the lining of the womb (menstrual period)

For the egg to be fertilised, it must encounter a sperm in the Fallopian tube. When you have sex, your partner releases millions of sperms into your vagina; some of the sperms travel up through the womb into the Fallopian tubes. If there is an egg in the Fallopian tube, one sperm will fertilise it. The fertilised egg will move towards the womb, become implanted in the lining and start growing into a baby.

If the egg does not encounter a sperm in the Fallopian tube and is not fertilised, it will be discarded with the lining of the womb at the end of the menstrual cycle and you will have a period.

It is important to know that:

- a released egg can live for up to 2 days;
- sperms can live for up to 5 days within a woman's body; so if you have unprotected sex up to 5 days before ovulation or a few days after it you may become pregnant.

HOW DO YOUR NATURAL HORMONES WORK?

Your ovaries make two hormones which control your menstrual cycle; these are called:

- oestrogen
- progesterone

During the first part of your menstrual cycle (before ovulation) your body is preparing itself for pregnancy; more oestrogen is produced because it makes the lining of the womb thicker so that a fertilised egg can grow in it.

During the second part of the cycle (after ovulation) more progesterone is produced. This stops the growth of the lining of the womb.

If the egg is not fertilised, the amounts of the two hormones decrease and this makes the lining of the womb break down. The lining will be discarded, together with the unfertilised egg as a menstrual bleed.

Pills such as MICRONOR® protect you against pregnancy because they contain a synthetic progestogen similar to that produced by your body. These pills thicken vaginal fluid so that sperm cannot get to the womb and they change the lining of the womb so that eggs cannot grow there.

HOW EFFECTIVE IS THE PILL?

The pill is an effective method of contraception if taken properly. So you must take the pill exactly as described in this leaflet (see section "HOW YOU SHOULD TAKE MICRONOR®").

It is important to remember that no form of contraception, not even the pill, can offer 100% protection against pregnancy. Pills such as MICRONOR® which only contain a progestogen are slightly less effective than "*combined*" pills (containing a progestogen and an oestrogen as well).

WHAT IS IN MICRONOR®?

Active ingredient:

MICRONOR® contains a progestogen hormone called norethisterone. Each tablet contains 350 micrograms norethisterone.

Other ingredients:

Lactose, pregelatinised starch, magnesium stearate.

WHAT SHOULD MICRONOR® LOOK LIKE?

Round white tablets engraved C 035 on both sides. Each pack contains 84 tablets (3 strips of 28 tablets each).

* Unmarketed pack sizes:

Each pack contains 28 tablets.

Each pack contains 42 tablets.

Each pack contains 84 tablets (2 strips of 42 tablets each).

Each pack contains 2800 tablets (100 strips of 28 tablets each).

WHAT TYPE OF MEDICINE IS MICRONOR®?

MICRONOR® is a progestogen-only oral contraceptive, also called the "*mini pill*".

WHO IS LICENSED TO SELL MICRONOR®?

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

RELEASED BY

Janssen Pharmaceutica NV
Turnhoutseweg 30
B-2340 Beerse
Belgium

WHAT IS MICRONOR® USED FOR?

MICRONOR® is used to prevent pregnancy.

HOW DO MICRONOR® TABLETS WORK?

1. They thicken vaginal fluid so that sperm cannot get to the womb.
2. They change the lining of the womb so that eggs are unable to grow there.

IS MICRONOR® SUITABLE FOR YOU?

Do not use these pills if:

- You are or think you may be pregnant
- You have a problem with your circulation, such as phlebitis or blood clots
- You have, or have ever had:
 - a heart attack
 - a stroke
 - jaundice of pregnancy or jaundice whilst taking the pill
- You have:
 - severe liver problems
 - liver tumours
 - tumours of the breast, womb or ovary
 - unusual or irregular vaginal bleeding which your doctor does not know about

If you are not sure about any of these conditions you should talk to your doctor. He/she will consider your medical history and decide whether this pill is suitable for you.

There are certain conditions which you may have, or have had in the past, where you can still use this pill but your doctor will have to monitor you more regularly. If you already have any of these, or you develop any whilst you are taking MICRONOR®, please tell your doctor - he/she can then decide whether you should continue to take this pill.

These include the following:

- fibroids of the womb
- raised blood sugar
- raised blood pressure
- depression

- fluid retention
- epilepsy
- migraine
- asthma
- heart or kidney problems
- varicose veins
- multiple sclerosis
- porphyria
- tetany
- problems with contact lenses
- amenorrhoea (lack of menstrual periods).

It is important to tell your doctor about any of these. If you are not sure about any you should discuss it with your doctor.

ARE YOU TAKING OTHER MEDICINES?

It is important that you tell your doctor about any other medicines you are taking including any that you have bought yourself. Some medicines may prevent MICRONOR® from working properly so that you could get pregnant. These include:

- some antibiotics and anti-fungal drugs
- barbiturates
- drugs that treat epilepsy

Your doctor will advise you whether or not you should use extra contraception.

The herbal remedy St John's wort should not be taken at the same time as this medicine. If you already take a St John's wort preparation, stop taking the St John's wort and mention it to your doctor at your next visit.

SPECIAL WARNINGS

- You should have talked to your doctor about any present and past medical problems. Your doctor will check your blood pressure and will decide whether you need any other examination before starting the pill. Your blood pressure should be checked regularly once you have started the pill.
- This pill should not be used for 6 weeks before an operation/surgery.

- This pill may affect the results of certain blood and urine tests - please tell the doctor/nurse that you are taking this pill when you have any such tests.
- If you do get pregnant while taking this pill there may be a slightly increased risk that it is an ectopic pregnancy (a pregnancy in the wrong place, i.e. outside the womb).
- Your periods may become irregular while you are on this pill i.e. the length of time between periods may vary. For example, you might have a 28-day cycle followed by a 17-day cycle followed by a 35-day cycle etc. This irregularity tends to be greater during the first few months.
- You should continue taking a pill every day whether you have a period or not but if you have gone 45 days without having a period, stop taking MICRONOR® and contact your doctor so that he/she can make sure you are not pregnant.
- Statistics show that women who take the "combined" pill have a higher risk of blood clots and thrombosis than those who don't. Blood clots and thrombosis can occur in different blood vessels causing problems such as a pulmonary embolus (blood clot in the lung), a stroke or a heart attack. These are rare but serious and may be fatal. Although an association between these disorders and progestogen-only pills (such as MICRONOR®) has not been shown, users of such pills might have an increased risk of thrombosis. The signs and symptoms of a blood clot are described under "Reasons for Stopping MICRONOR® Immediately"; if you develop any of those signs or symptoms, stop taking MICRONOR® at once and see your doctor.
- There is an increased risk of thrombosis on the first days following childbirth and your doctor should consider this when prescribing this pill.
- A small amount of progestogen may pass into the milk of mothers taking this pill. The effects, if any, on the breast-fed child have not been determined.
- Once you have stopped this pill to try to become pregnant, it may take you a while to conceive.
- Tell medical staff you are using MICRONOR®, for example, if you go into hospital or see a dentist or doctor.

HOW YOU SHOULD TAKE MICRONOR®:

It is important to take this pill as your doctor told you and as stated below:

1. When to start

- Start taking MICRONOR® on the first day of your period; if you do this no extra contraceptive cover is required.

2. How to take MICRONOR®

- Each tablet should be swallowed whole.
- MICRONOR® comes in a pack marked with the days of the week. Take your first pill marked with the right day (i.e. if your period starts on a Tuesday, the first pill you take should be marked Tuesday).
- Each day take the pill for that day and do this for the 28 pills in the pack. **Take your pill at about the same time each day** - most people find it easier to remember taking it before bedtime.
- When you have taken all the 28 pills and the pack is empty, **start a new pack on the very next day.**
- Continue with this pack and future packs in the same way as described above i.e. one tablet at the same time each day, every day of the year.
- **There must never be a break between packs.**
- You should keep on taking the pill even when you are having a period.

3. After having a baby

- You can start using MICRONOR® on the 21st day after your baby is born. This gives you contraceptive protection immediately.
- If you start MICRONOR® later than this, you should use extra contraception (see "EXTRA CONTRACEPTION" section) for the first 7 days of pill taking.

4. After miscarriage or abortion

- You can start taking MICRONOR® on the first day after a miscarriage or abortion. This gives you contraceptive protection immediately.
- Ask your doctor about other contraception if you are not starting MICRONOR® immediately.

5. Changing from another type of pill What sort of pill were you on?

(i) 21 day pill

- Finish the pack of contraceptive pills you are on. Start taking MICRONOR® on the very next day. Do not leave a break between packs or wait for your period to begin.

(ii) Another brand of mini pill (progestogen-only pill)

- Finish the pack of contraceptive pills you are on. Start taking MICRONOR® on the very next day. Do not leave a break between packs or wait for your period to begin.

(iii) Every day pill ('ED' pack)

- Finish the first 21 pills of your 'ED' pack. Take your first MICRONOR® pill the next day. Do not leave a break between packs or wait for your period to begin.

WHAT MIGHT STOP YOUR PILL WORKING?

- **Forgetting to take a pill**

If you are more than 3 hours late, this pill may not work

If you forget to take a pill, check when your missed pill was due and then follow the instructions in the "MISSED PILL GUIDE".

- Having a stomach upset (vomiting/diarrhoea)

If you have vomiting or diarrhoea, carry on taking MICRONOR® as usual but also use extra contraception for as long as you are ill and for the next 7 days after that.

MISSED PILL GUIDE:

1. When was your missed pill due?

- | | |
|--|--|
| <ul style="list-style-type: none">• Less than 3 hours ago<ul style="list-style-type: none">– Don't worry– Take the forgotten pill now– Take the rest of your pills at the usual times– That's all | <ul style="list-style-type: none">• More than 3 hours ago<ul style="list-style-type: none">– Take the latest pill now– Take the rest of your pills at the usual times– Use extra contraception for the next 7 days– If you do not have a period within 45 days of your last period, stop taking MICRONOR® and see your doctor at once |
|--|--|

EXTRA CONTRACEPTION

It is important that extra contraception is used in the following situations:

- If you are more than 3 hours late in taking a pill
- If you have a stomach upset (vomiting/diarrhoea)

You should still take your MICRONOR® pill each day but use other contraception as well for 7 days after any of these events.

EXTRA CONTRACEPTION

You can use

- a condom
- a cap or diaphragm with a spermicide
- a contraceptive sponge

If you use any of these, follow the instructions carefully

WHAT TO DO IF YOU TAKE TOO MANY MICRONOR® PILLS?

If a large number of these pills are taken, contact your doctor for advice. There have been no reports of serious problems from an overdose of MICRONOR®.

HOW SAFE IS THE PILL?

It is important to know that even if a product has been used by a great number of patients for a large number of years, it is not possible to guarantee that the product is completely safe for all patients, because each person is unique. So, with the pill (as with any other medicine), some risk to health must be accepted.

WHAT SIDE EFFECTS MAY MICRONOR® HAVE?

As with any other oral contraceptive pill, MICRONOR® may cause some unwanted effects but this is not common. The following unwanted effects have been reported:

- headaches
- migraine
- nausea
- vomiting
- breast changes
- changes in weight
- changes in sex drive
- patches of darkened skin
- rash
- depression
- breakthrough bleeding and spotting
- irregular cycle length
- benign liver tumours

- malignant liver tumours (reported on rare occasions in long-term users of the pill).
- If such effects occur and become troublesome, frequent and/or more severe, please consult your doctor for advice.
- Never miss your check ups with your doctor. Your doctor can check for side effects which you may not notice yourself.
- Tell your doctor or pharmacist if you notice any other unwanted effect not mentioned above.

Breast Cancer

Every woman is at risk of breast cancer whether or not she takes the pill. Breast cancer is rare under 40 years of age but the risk increases as a woman gets older.

Breast cancer has been found slightly more often in women who take the pill than in women of the same age who do not take the pill. If women stop taking the pill, this reduces the risk, so that 10 years after stopping the pill, the risk of finding breast cancer is the same as for women who have never taken the pill. Breast cancer seems less likely to have spread when found in women who take the pill than in women who do not take the pill.

It is not certain whether the pill causes the increased risk of breast cancer. It may be that women taking the pill are examined more often, so that breast cancer is noticed earlier. The risk of finding breast cancer is not affected by how long a woman takes the pill, but by the age at which she stops. This is because the risk of breast cancer strongly increases as a woman gets older.

In 10,000 women who take progestogen-only pills like MICRONOR® for up to 5 years, but stop taking it by the time they are aged 20, it is estimated that less than one additional case of breast cancer would be found up to 10 years afterwards compared with the number found in 10,000 women who had never taken the pill. For 10,000 women who take a pill like MICRONOR® for 5 years and stop it by the age of 30, there would be 2 or 3 extra cases of breast cancer found up to 10 years afterwards (in addition to the 44 cases of breast cancer found in 10,000 women in this age group who had never taken the pill).

For 10,000 women who take MICRONOR® for up to 5 years and stop it by the age of 40, there would be about 10 extra cases found up to 10 years afterwards (in addition to 160 cases of breast cancer found in 10,000 women in this age group who had never taken the pill).

The possible small extra risk of being diagnosed with breast cancer has to be weighed against the known benefits of taking the progestogen-only pill.

If anything is unclear about this you should ask your doctor about it at your next routine visit.

REASONS FOR STOPPING MICRONOR® IMMEDIATELY:

You must stop using MICRONOR® immediately and consult your doctor if:

- you experience any of the following signs/symptoms of a blood clot
 - severe pain or tenderness or swelling in the calf of one or both legs.
 - unexpected chest pain, shortness of breath or coughing up blood.
 - unexpected numbness, tingling, severe headache, dizziness, fainting, fitting, problems with eyesight or speech.
 - unexpected stomach pain.
- veins in your legs become painful or inflamed
- you experience a crushing type of chest pain or simply heaviness in your chest
- you develop migraine or your existing migraine worsens
- you notice a swelling and/or tenderness in the upper part of your tummy
- you become jaundiced
- you are to have an operation/major surgery
- you have to take bed rest or remain immobile for a long time
- you know or suspect that you may be pregnant, since progestogens taken in early pregnancy (although in much higher doses than that contained in MICRONOR®) can affect the normal development of the child.

WHAT IF YOU DECIDE TO HAVE A BABY

It is best to wait until your regular periods have returned so that your doctor is able to work out when the baby is due. So, once you have stopped taking MICRONOR® because you wish to try to become pregnant, use another method of contraception until your regular periods return.

If you get pregnant immediately after stopping the pill, this is not harmful.

HOW SHOULD YOU STORE MICRONOR®?

- Store at room temperature (below 25°C); protect from light.

Other important points:

- Keep out of reach of children

Do not use these tablets:

- After the expiry date shown on the label
- If the tablets do not look as described above

Date of revision of this leaflet: February 2009

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