

MICRONOR[®]

Norethisterone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MICRONOR tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given MICRONOR against the benefits this medicine is expected to have for you.

If you have any concerns about using MICRONOR ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What MICRONOR is used for

MICRONOR is used to prevent pregnancy.

MICRONOR is a birth control pill (also known as an oral contraceptive). Unlike other oral contraceptives, MICRONOR only contains one type of female hormone, called progesterone. This makes MICRONOR a progesterone only contraceptive pill or 'mini pill'.

The active ingredient in MICRONOR is norethisterone which is rapidly absorbed from the gastrointestinal tract.

Norethisterone is a synthetic progestogen (hormone) and is known to alter the cervical mucus and lining of the womb. As a result there is a reduced chance of fertilisation (sperm reaching the egg). It also makes it harder for any fertilised egg to become attached to the wall of the womb and therefore less likely for pregnancy to occur.

Your doctor may have prescribed MICRONOR for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Like all oral contraceptives, MICRONOR is intended to prevent pregnancy. It does not protect against HIV infection and other sexually transmitted diseases (see **Special Precautions**)

Before you use MICRONOR

When you must not use it

Do not use MICRONOR if:

- you have hypersensitivity to progesterone or any component of this product.
- you have or previously had high blood pressure, stroke, heart attack or problems with blood clots in blood vessels.
- you have known or suspected cancer of the breast, vagina, cervix, ovaries or womb.
- you have unexplained vaginal bleeding.
- you have a benign or malignant liver tumour, or family history of liver diseases. Yellowing of the skin or eyes or generalised itching of the skin during previous pregnancies (known as Dubin-Johnson Syndrome or Rotor Syndrome).
- you are pregnant, or think you are pregnant (unless otherwise instructed by your doctor).
- you have an inherited blood condition known as sickle cell anaemia.
- you have a disorder with lipid metabolism, such as high cholesterol.
- you have experienced herpes during previous pregnancies.
- you have a hearing disorder known as Otosclerosis, which worsened while you were pregnant in the past.

Do not take MICRONOR if:

- the packaging is torn or shows signs of tampering.
- the expiry date (month and year) printed on the pack has passed.

Before you start to use it

Before prescribing MICRONOR your doctor may need a complete medical and family history. A physical examination is desirable, including special reference to blood pressure, breasts, abdomen and pelvic organs, including Papanicolaou smear and laboratory tests.

Your doctor may need to monitor you more closely in some instances.

Tell your doctor if you are breastfeeding or intend to breastfeed.

Tell your doctor if you have or have ever had:

- liver diseases (including tumours of any type) yellowing of the skin or eyes or a generalised skin itch during previous pregnancies. (known as Dubin-Johnson Syndrome or Rotor Syndrome)
- unusual vaginal bleeding and have not been seen by a doctor
- family history of breast cancer, blood clotting disease or heart disease
- epilepsy
- diabetes
- high blood pressure
- endometriosis (condition in which material similar to the lining of the womb grows outside the womb, causing pain or bleeding)
- diseases effecting calcium or phosphorous metabolism such as osteoporosis
- asthma
- liver or kidney function impairment
- heart problems
- depression
- oedema
- distributed lipid metabolism
- past history of arterial/CV disease
- migraine or severe headaches
- past ectopic pregnancy
- high blood cholesterol levels
- headaches or migraine

Taking other medicines

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

In particular, tell your doctor or pharmacist if you are taking any of the following:

- rifampicin (used to treat tuberculosis and meningococcal disease)
- barbiturates, carbamazepine (used to treat epilepsy)
- phenylbutazone (used to reduce pain and inflammation)
- phenytoin sodium (used to treat epilepsy)
- ampicillin (an antibiotic)
- bosentan (a medicine used to treat hypertension)
- indinavir, ritonavir (used to treat HIV infection)
- topiramate (used to treat epilepsy and migraine)
- griseofulvin (used to treat fungal infections)
- St. John's wort (used to relieve anxiety).

These medicines may be affected by MICRONOR or may affect how well MICRONOR works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

Special Information

Discuss with your doctor the risks of sexually transmitted diseases and the use of other contraceptive barriers that may be required to reduce the risk of transmission of human papilloma virus.

A physical examination is desirable, including Papanicolaou smear and laboratory tests.

Discuss with your doctor the increased risk of conditions such as stroke, heart disease, hypertension and gall bladder disease associated with oral contraceptive use.

Discuss with your doctor the increased risk of cervical cancer associated with oral contraceptive use. However the relationship between progesterone-only oral contraceptives and these risks have not been fully defined.

Using MICRONOR

How to use it

Your packet of MICRONOR contains 4 x 28 tablets, each white tablet contains 0.35 mg of norethisterone. Each tablet is marked on each side with C035.

It is important that the tablets be used in the correct sequence to ensure regular cyclic bleeding.

Directions:

- To begin taking MICRONOR, the first tablet should be taken on the first day of your next period.
- This is the day your bleeding starts
- Begin by taking the tablet which corresponds to the appropriate day of the week. If for example your first day of bleeding is on Wednesday you should take a tablet from the section marked 'WED'
- Continue to take one tablet everyday following the direction of the arrows around the strip, coinciding with the days of the week until all tablets are finished.
- You should take a tablet at approximately the same hour each day.
- When you have finished your first strip of tablets, start the next strip of tablets the following day and take one tablet every day following the direction of the arrows around the strip.
- Continue taking the tablets even when you are having a period.
- This sequence of tablet taking is continued as long as birth control is required.

If you do not understand the instructions provided with this medicine it is important to ask your doctor or pharmacist for help.

If you forget to use it

- If you have missed a pill or it has been more than 3 hours (but less than 24 hours) since you had meant to take your pill, take it (the missed pill) as soon as possible (catch-up pill), and then take the next pill when you are meant to. Do this even if it means you take two pills in one day.
- In addition, to ensure continual protection from getting pregnant, continue taking the pill as normal and use a non-hormonal method of contraception (such as condoms and/or diaphragms) for the next 48 hours following the catch-up pill.
- If you have missed taking a pill for one complete day (24 hours), take two pills as soon as possible, then resume taking pills at the regularly scheduled time. You should also consult your doctor.
- If you have missed taking a pill for more than 24 hours, stop taking MICRONOR and use a non-hormonal contraception (such as condoms or diaphragms) until menses appear or pregnancy is excluded.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you have used too much (overdose)

Overdosage may cause nausea, vomiting and, in young girls, vaginal bleeding. Immediately telephone your doctor or the Poisons Information Centre for advice, or go to casualty at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Poisons Information Centre telephone numbers:

- **Australia: 13 11 26**
- **New Zealand: 0800 764 766 or 0800 POISON**

Keep these telephone numbers handy.

While you are using MICRONOR

Things you must do

- MICRONOR tablets should be taken exactly as directed and at intervals not exceeding 24 hours
- Always follow your doctor's instructions carefully
- Tell your doctor if the following occurs, and stop taking MICRONOR and use a non-hormonal method of contraception (such as condoms and/or a diaphragm) until pregnancy is ruled out:
 - If you have not had a period within 45 days from your last period. You may be pregnant.
 - If you have taken MICRONOR as instructed and you have missed two consecutive periods.
- If you are about to start taking a new medicine, tell your doctor or pharmacist that you are taking MICRONOR.
- Always have your next pack of pills ready, as there is no break between packs.
- You should visit your doctor regularly for medical check ups, which may include blood tests.
- If you are fully breastfeeding (not giving your baby any food or formula) you may start MICRONOR 6 weeks after delivery.
- If you are partially breastfeeding (giving your baby some food or formula) you may start MICRONOR 3 weeks after delivery.
- See your doctor if you notice any unusual physical changes or discomfort while using MICRONOR and these worry you.

During time of illness:

If you get sick and vomiting or diarrhoea occurs within 2 hours of taking the pill, take an extra pill as soon as you are able to; and continue taking the pills on schedule if possible.

If you are unable to take an extra pill within 2 hours of your regularly scheduled time, stop taking MICRONOR and use a non-hormonal contraceptive (such as condoms and/or diaphragm). Use the non-hormonal contraceptive method until menses appear or pregnancy is excluded.

Things you must not do

- Do not use MICRONOR to treat any other complaint unless your doctor says so.
- Do not give this medicine to anyone else, even if they are using the same type of birth control as you. You will need all the tablets in the pack for birth control to be effective.
- You should not smoke as smoking increases the risk of blood clotting and damage to the heart and blood vessels. The risk increases with age and with heavy smoking (15 or more cigarettes per day), especially in women over the age of 35.

Side Effects

Tell your doctor as soon as possible if you do not feel well while you are using MICRONOR

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects.

Do not be alarmed by this list of possible side effects, as you may not experience any of them.

Tell your doctor immediately or go to emergency at your nearest hospital if the following happens:

- If you experience unexplained, sudden/severe or persistent pains in the head, chest, stomach (abdominal pain) or legs.
- if there is a gradual or sudden, partial or complete loss of vision

Tell your doctor immediately if the following happens, as you may need medical attention:

- if you develop sore veins especially in the legs or groin, unusually severe headaches, problems with your heart or if you experience any other event related to blood clotting
- swelling of the eye(s) or eye lesions
- yellowing of the skin or eyes
- you have unusual or prolonged vaginal bleeding or spotting

These may require medical attention.

Tell your doctor if the following happens

- nausea, vomiting and other stomach discomforts, these often decrease with continued use
- change in menstrual flow
- breakthrough vaginal bleeding or spotting
- changes in weight (weight gain or weight loss)
- changes in skin colour (darkening or blotchiness)
- absence of periods or painful periods
- skin rashes, acne
- breast changes (including tenderness, enlargement and/or secretion)
- migraine or severe headaches
- dizziness
- abdominal cramps / bloating
- vaginal thrush, bladder irritation
- mental depression
- Androgenic side effects (such as hirsutism), acne and weight gain.

These are mild side effects. Ask your doctor for advice if they worry you.

Do not hesitate to report any other side effects to your doctor.

After using MICRONOR

Storage

- Keep MICRONOR tablets in the pack until it is time to take them.
- Keep MICRONOR in a cool dry place where the temperature is at or below 25°C.
- Do not store it or any other medicines in the bathroom or near a sink. Do not leave medicines in the car or on the window-sills. Heat and dampness can destroy some medicines.
- Keep it where young children or pets cannot reach it. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.
- Do not use MICRONOR beyond the date (month and year) printed on the pack after the letters "EXP", even if it has been stored properly. Medicines cannot be stored indefinitely.

Disposal

If your doctor tells you to stop taking MICRONOR tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product Description

What it looks like

Each MICRONOR tablet is white and round.

Each MICRONOR tablet is marked on each side with "C035".

MICRONOR is available in a carton containing 4 blister packs. Each blister pack contains 28 tablets.

Ingredients

The active ingredient of MICRONOR tablets is 0.35 mg of norethisterone.

Excipients are lactose, starch, pre-gelatinised maize and magnesium stearate as the inactive ingredients.

Sponsor

Janssen-Cilag Pty Ltd
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Australia

Australian Registration Number: MICRONOR AUST R 13304

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