



Mikrolon™ is a 21-day pill, to take one each day for 21 days, followed by 7 days when you take no pills. It is a combined oral contraceptive pill to prevent getting pregnant. This low dose contraceptive contains two types of female sex hormones, Oestrogen and Progestogen. These hormones prevent an egg being released from the ovaries to prevent getting pregnant. **Mikrolon™** also makes the cervical fluid (mucus) thicker to make it more difficult for sperm to enter the womb. It does not protect from sexually transmitted diseases (STD).

Composition

Each tablet contains Desogestrel BP 0.15 mg & Ethinylestradiol USP 0.02 mg.

The benefits of taking the pill include:

- It is one of the most reliable reversible methods of contraception if used correctly
- It does not interrupt sex
- It usually makes period regular, lighter and less painful
- It may help with pre-menstrual symptoms

When you should not use Mikrolon™

You should not use **Mikrolon™** if you have or ever had any of the conditions listed below:

- A blood clot in a blood vessel of legs (Deep Vein Thrombosis, DVT), lungs (Pulmonary Embolus, PE) or other organs
- A disorder affecting blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or anti phospholipid antibodies
- Need an operation or off to feet for a long time
- A heart attack or stroke
- Angina pectoris
- Any of the following diseases that may increase risk of a clot in the arteries:
 - Severe diabetes with blood vessel damage
 - Very high blood pressure
 - A very high level of fat in the blood (cholesterol or triglycerides)
 - A condition known as hyperhomocysteinaemia
- A type of migraine called 'migraine with aura'
- A severe liver disease or liver tumour
- Cancer affected by sex hormones – such as some cancers of the breast, womb lining or ovary
- Vaginal bleeding that has not been explained by doctor
- Allergy (hypersensitivity) to any of the ingredients in **Mikrolon™**

If you suffer from any of these, or get them for the first time while taking **Mikrolon™** contact your doctor as soon as possible stop taking **Mikrolon™**.

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 **Mikrolon™**. Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

Some medicines can stop **Mikrolon™** from working properly-for example:

- Some medicines used to treat epilepsy (Primidone, Phenytoins, Barbiturates, Carbamazepine, Oxcarbazepine, Topiramate, Felbamate)
- Medicine to treat tuberculosis (Rifampicin)
- Certain HIV medicines (Ritonavir)
- Certain antibiotics (Penicillins, Tetracyclines)
- St. John's Wort (a herbal remedy)
- Griseofulvin (an antifungal drug)

If you do need to take one of these medicines, **Mikrolon™** may not be suitable for you or you may be able to take **Mikrolon™** and use extra contraception for a while. **Mikrolon™** can also affect how well other medicines work. For example, Cyclosporine and Lamotrigine.

Taking Mikrolon™ with food and drink

There are no special instructions about food and drink while on **Mikrolon™**.

Pregnancy and breast-feeding

Do not use **Mikrolon™** if you are pregnant. If you think you might be pregnant, do a pregnancy test to confirm that you are before you stop taking **Mikrolon™**. **Mikrolon™** is not recommended for use during breast-feeding. Ask your doctor or family planning nurse about alternative contraception.

Taking Mikrolon™

Take **Mikrolon™** every day for 21 days as described below:

Mikrolon™ comes in strips of 21 pills, each marked with a day of the week.

- Take your pill at the same time every day.
- Start by taking a pill marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 21 pills.
- Swallow each pill whole, with water if necessary. Do not chew the pill.
- After you have taken all 21 pills in the strip, you have seven days when you take no pills. So, if you take the last pill of one pack on a Friday, you will take the first pill of your next pack on the Saturday of the following week.

Within a few days of taking the last pill from the strip, you should have a withdrawal bleed like a period. This bleed may not have finished when it is time to start your next strip of pills.

You don't need to use extra contraception during these seven pill-free days.

Starting Mikrolon™

As a new user or starting the pill again after a break. Either take your first **Mikrolon™** pill on the first day of your next period. By starting in this way, you will have contraceptive protection with your first pill.

Or if your period has already begun start taking **Mikrolon™** on day 5 (counting the first day of your period as day 1) whether or not your bleeding has stopped. You must also use extra contraception, such as condoms, until you have taken the first seven pills correctly.

Changing to Mikrolon™ from another contraceptive Pill

- If you are currently on a 21-day pill, start taking **Mikrolon™** the next day after the end of the previous strip. You will have contraceptive protection with your first pill but you will not have a bleed until after you finish your first strip of **Mikrolon™**.
- If you are currently on a 28-day pill, start taking **Mikrolon™** the day after your last active pill. You will have contraceptive protection with your first pill.
- You will not have a bleed until after you finish your first strip of **Mikrolon™**.
- Or if you are taking a Progestogen-only Pill (POP), start **Mikrolon™** on the first day of bleeding, even if you have already taken the POP for that day. You will have contraceptive cover straight away. If you don't usually have any bleeding while you are taking a Progestogen-only Pill, you can stop taking it any day and start **Mikrolon™** the next day. You will need to use extra contraception, such as a condom, for seven days.
- Changing to **Mikrolon™** from a Progestogen-only injection, implant of Progestogen releasing intrauterine device (IUD). Start taking **Mikrolon™** when your next injection is due or on the day that your implant or IUD is removed. Make sure you also use an additional contraceptive method, such as a condom, for the first 7 days that you are taking **Mikrolon™**.

Starting Mikrolon™ after a miscarriage or abortion

If you have had a miscarriage or an abortion, your doctor may tell you to start taking **Mikrolon™** straight away. This means that you will have contraceptive protection with your first pill. Contraception after having a baby if you have just had a baby, ask your doctor for advice about contraception.

If you are not breast-feeding:

- You can start taking **Mikrolon™** three weeks after the birth or more than three weeks after the birth but you need to use extra contraception, such as a condom until you have taken the first seven pills correctly.
- If you have had sex since the birth there is a chance that you could be pregnant, you should therefore use another form of contraception, such as a condom. In this case, take your first **Mikrolon™** pill on the first day of your next period.

A missed pill

If you have missed any of the pills in a strip and you do not bleed in the first pill-free break, you may be pregnant. Contact your doctor or family planning clinic or do a pregnancy test yourself.

If you start a new strip of pills late or make your "week off" longer than seven days, you may not be protected from pregnancy.

If you had sex in the last seven days, ask your doctor, family planning nurse or pharmacist for advice. You may need to consider emergency contraception. You should also use extra contraception, such as a condom, for seven days.

A lost pill

If you lose a pill, either take the last pill of the strip in place of the lost pill. Then take all the other pills on their proper days. Your cycle will be one day shorter than normal, but your contraceptive protection won't be affected. After your seven pill-free days you will have a new starting day, one day earlier than before.

If you are sick or have diarrhoea

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

If you vomit within 3 to 4 hours after taking your pill, this is like missing a pill.

You must follow the advice for missed pills.

If you have severe diarrhoea for more than 12 hours after taking **Mikrolon™** follow the instructions for if you are more than 12 hours late. A missed pill.

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

Missed a period – could you be pregnant?

Occasionally, you may miss a withdrawal bleed. 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.

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.

You can delay a period

If you want to delay having a period, finish the strip of pills you are taking. Start the next strip the next day without a break. Take this strip the usual way. After the second strip, leave seven pill-free days as usual, then start your next strip of pills in the normal way. When you use the second strip, you may have some unexpected bleeding or spotting on the days that you take the pill, but don't worry.

When you want to get pregnant

If you are planning a baby, it's best to use another method of contraception after stopping **Mikrolon™** until you have had a proper period. Your doctor or midwife relies on the date of your last natural period before you get pregnant 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.

Side Effects

Common:

- Migraine or headache (see a doctor as soon as possible if this is your first migraine or it's worse than usual, or if the headache is severe, unusual or long lasting)
- Putting on weight or losing weight
- Breast problems, such as painful or tender breasts; producing a milky fluid from the nipples
- Depression or mood changes
- Changes in sexual desire
- Heart or circulation problems, such as increased blood pressure, swollen hands, ankles or feet (a sign of fluid retention)
- Changes in vaginal secretions (Irregular vaginal bleeding)
- Skin problems; such as, rash, bruise-like swelling to the shins (erythema nodosum)
- Stomach problems; such as, nausea, vomiting
- Discomfort of the eyes who wears contact lenses

Rare (and/or severe):

- Harmful blood clots in a vein or artery or other blood vessels leading Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), heart attack, stroke or Transient Ischemic Attack (TIA)
- Blood clots in the liver, stomach/intestine, kidneys or eyes
- Breast and/or cervical cancer
- Hypersensitivity reactions

If you think you may have any of these, see a doctor straight away. You may need to stop taking **Mikrolon™**.

Bleeding between periods should not last long

A few women have a little unexpected bleeding or spotting while they are taking **Mikrolon™**, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking **Mikrolon™** 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 **Mikrolon™** for a while
- Carries on even after you've stopped taking **Mikrolon™**

How to store Mikrolon™

Store in a cool & dry place, protect from light & moisture. Keep out of the reach of children.

Commercial Pack

Each box contains 1 x 21's tablets in Alu-PVC blister strip in a sealed sachet of 21's.



Manufactured by:
Nuvista Pharma Limited
48 Tongi industrial area, Gazipur, Bangladesh
A subsidiary of Beximco Pharmaceuticals Ltd.

0111DS1601