MICR CTAB PL SH 040914

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Microlut®

Film-coated tablets

Each film-coated tablet contains:
Levonorgestrel 0.03 mg
Inactive ingredients and allergens: see section 6 "Further Information".

Read this leaflet carefully in its entirety before using the medicine.
This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

ESSENTIAL INFORMATION ABOUT THE MEDICINE

- This medicine does not protect against sexually transmitted diseases (such as AIDS or chlamydia); only a condom helps with this.
- This medicine is not appropriate for some patients, due to their medical condition. Please read the leaflet to ensure that Microlut is suitable for you.
- This medicine may increase your risk of experiencing effects such as blood clots and breast cancer.
- To prevent pregnancy, it is important that you take Microlut as instructed and begin a new pack on time. Please make sure that you understand what you are supposed to do in case you forget a pill or if you think you are pregnant.

1) WHAT IS THE MEDICINE INTENDED FOR?

Microlut is intended to prevent pregnancy.

Therapeutic group: Microlut belongs to a group of medicines called progestogen hormones and acts as a contraceptive in three ways: thickening of the cervical discharge, making penetration of sperm into the uterus more difficult, prevention of the thickening of the uterine walls, necessary for implantation of the egg, and in some patients, prevention of ovulation.

2) BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine. For the list of inactive ingredients, see section 6 "Further Information".
- you are pregnant or there is a chance you are pregnant.
- you are suffering, or have suffered in the past, from acute liver disease and you have been told by your doctor that your liver function has still not returned to its normal level.
- you are suffering, or have suffered in the past, from liver tumors.
- you are suffering, or have suffered in the past, from cancer affected by sex hormones, such as certain types of breast cancer.
- you are suffering from unexplained vaginal bleeding.
- you are suffering from a blood system problem, including a blood clot in the legs (deep-vein thrombosis), in the lungs (pulmonary embolism), in the heart (heart attack), in the brain (stroke), or in other parts of the body.
- you have severe diabetes that affects your blood vessels.

In such cases, taking Microlut may endanger your health.

If you are suffering from one of the above-mentioned conditions, or if you experience one of them for the first time, contact your doctor as soon as possible. In such cases, do not use Microlut, but rather, use another method of contraception.

Special warnings regarding use of the medicine

Before starting treatment, or in order to make a decision regarding continuation of treatment, it is important that you understand the advantages and disadvantages of taking Microlut. Although Microlut is suitable for most healthy women, it is not suitable for everyone.
Inform the doctor if you are suffering from the medical conditions or risk factors mentioned in this leaflet.

Before treatment with Microlut, tell the doctor if you are suffering, or have suffered in the past, from the following diseases or conditions:

- Diabetes
- If you have had an ectopic pregnancy or impaired fallopian tube function in the past
- Ovarian cysts
- Yellowing of the skin (jaundice)
- Persistent itching
- Chloasma (pigmented spots on the skin, especially the face) – if so, avoid prolonged exposure to the sun or to ultraviolet rays.

Some of the conditions mentioned above may become worse when taking Microlut, or they may indicate that Microlut is not suitable for you.
Tell the doctor if one of the conditions or diseases mentioned above applies to you, or first occurred to you when taking Microlut, or you have had them in the past or they worsened during pregnancy or when taking another hormonal contraceptive, since the doctor may instruct you to stop using Microlut.

The pill and blood clots

Use of Microlut may increase your risk of a blood clot (called thrombosis), especially during the first year of use.
A blood clot in the vein of the leg – deep venous thrombosis (DVT) – is not always serious. However, if the blood clot migrates in the veins and blocks one of the pulmonary arteries, chest pain, shortness of breath, collapse and even death, may occur. This condition is called a pulmonary embolism and is very rare.
In rare cases, blood clots can form in the blood vessels of the heart (consequently leading to a heart attack), or the brain (consequently leading to a stroke). In healthy women, the risk of having a heart attack or stroke is very low.
The risk of a blood clot increases:

- With age
- If you smoke
- If you are severely obese
- If you have diabetes
- If you suffer from migraines
- If you are immobile for a prolonged period of time, due to surgery, injury or a disease
- If you, or one of your close family members suffered from blood clots
- If you are suffering from varicose veins

Tell the doctor if any of the conditions listed above apply to you. Taking Microlut may add to the existing risk; Microlut may therefore not be suitable for you.

Signs indicating a blood clot:

- Development of a migraine for the first time, worsening of a migraine, or development of severe or more frequent headaches
- Sudden changes in vision (e.g., loss of eyesight and blurred vision)
- Sudden changes in hearing, speech, sense of smell, taste or touch
- Pain or swelling of the leg
- Stabbing pain when breathing
- Coughing for no obvious reason
- Pain and tightness in the chest
- Sudden weakness or numbness on one side of your body
- Dizziness or fainting

Refer to the doctor as soon as possible. Stop using Microlut until instructed otherwise by the doctor. In the meantime, use a different contraceptive method, such as a condom.

The pill and cancer

If you have breast cancer or have had it in the past, it is recommended that you will not use Microlut. Microlut slightly increases your risk of developing breast cancer. This increased risk persists for as long as you are taking Microlut, but returns to normal within 10 years of discontinuing use. Since breast cancer is rare among women below the age of 40, the additional cases diagnosed in women taking or who had recently taken Microlut were few. For example:

- In 10,000 women who took progestogen-only pills, like Microlut, for up to 5 years and stopped taking it by the time they reached the age of 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 of cases of breast cancer found in 10,000 women who had never taken the pill.
- In 10,000 women who took progestogen-only pills, like Microlut, for up to 5 years and stopped taking it by the time they reached the age of 30, it is estimated that 2 or 3 extra cases of breast cancer would be 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).
- In 10,000 women who took progestogen-only pills, like Microlut, for up to 5 years and stopped using the pill by the time they reached the age of 40, it is estimated that approximately 10 extra cases of breast cancer would be 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).

Your risk of developing breast cancer increases:

- If you have a close relative (mother, sister or grandmother) who has had breast cancer.
- If you are severely obese.

Refer to the doctor immediately if you notice changes in the breasts, such as dimples in the skin, nipple changes or if you notice or feel any lumps.

Taking Microlut has been associated with liver diseases, such as jaundice and non-cancerous liver tumors, but these are rare. Even more rarely, Microlut has also been associated with some forms of liver cancer in women who took the medicine for a long time.
Refer to the doctor immediately if you experience severe abdominal pain, or yellowing of the whites of the eyes (jaundice). You may need to stop using Microlut.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is especially important to inform the doctor or pharmacist if you are taking any of the following medicines that can impair the activity of Microlut:

- Medicines for the treatment of epilepsy
- Medicines for the treatment of AIDS
- Aprepitant to treat severe vomiting
- Bosentan to treat pulmonary hypertension
- Griseofulvin to treat fungal infections
- Certain antibiotics
- Barbiturates given as sedatives
- The St. John's wort herb (*Hypericum*)

Microlut may affect the blood levels of other medicines, such as:

- Ciclosporin (its blood levels may rise)
- Lamotrigine (its blood levels may drop)

Microlut may also increase or decrease the effects of some anticoagulants (e.g., coumarins) or inhibit the anticoagulant effect of such types of medicine (e.g., phenindione).
If you are taking any of the medicines listed above, Microlut may not be suitable for you and you will need to use another contraceptive for some time. The doctor will tell you if this is necessary and for how long.
In addition, it is recommended that you check the leaflets of the medicines you are taking to see whether they can be taken in parallel to use of hormonal contraceptives.

Use of the medicine and food

The medicine can be taken either on an empty stomach or with food.

Pregnancy and breastfeeding

Do not take Microlut if you are pregnant.
If you think you may be pregnant, perform a pregnancy test before discontinuing use of the medicine.
If you became pregnant while using the medicine, stop taking it immediately and refer to the doctor.
No negative effect of use of Microlut on breast milk or on development of infants has been found.

Driving and use of machinery

There is no known effect of Microlut on ability to drive and to operate machinery.

Smoking

If you smoke, inform the doctor before commencing treatment with this medicine.
The risk of arterial thrombosis, associated with use of contraceptive pills, increases with age. This risk increases in women who smoke large quantities of cigarettes.

Important information regarding some of the ingredients of the medicine

Microlut contains lactose and sucrose. If your doctor has told you that you have an intolerance to certain sugars, consult the doctor before commencing treatment with Microlut.

3) HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

- The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally one tablet per day at a set time, for 35 days.

Do not exceed the recommended dose.

- How to take

Swallow the tablet whole, with water, if necessary, every day at the same time.
Be sure that you never take the tablet more than 3 hours late, otherwise, the contraceptive efficacy of the tablet will be reduced.
Do not crush/halve/chew, so as not to damage the coating of the tablet.
Take one Microlut tablet each day for 35 days.
Each pack has 35 tablets; each tablet is labeled at the back of the tray with a day of the week.
Take the tablet at a set time each day. Take the first tablet labeled with the correct day of the week. Follow the direction of the arrows on the back of the tray and take one tablet each day until you have taken all 35 tablets.
Start the next pack the day after completing the previous pack, while continuing to take a tablet labeled with the correct day of the week. Always start a new pack on time.
Continue taking Microlut during your period, without a break between completion of one pack and starting of a new pack.
If you took Microlut correctly, you will always start a new pack on the same day of the week.

- Starting use of Microlut
  - First use or after a break
    It is best to start taking Microlut on the first day of your period. In such cases, another method of contraception will not be required.
  - Switching to Microlut after using another contraceptive
    If you are currently taking a combined oral contraceptive: Start taking Microlut the day after your last active pill (discard the placebo pills or disregard the pill-free interval). Another method of contraception is not required.
    Changing from another progestogen-only pill: You can start taking Microlut at any time without the loss of contraceptive protection.
    Changing from a progestogen-only contraceptive method (implant, contraceptive injection): An additional non-hormonal contraceptive (e.g., a condom) is not required if you start taking Microlut on the exact day that the next injection or implant is due.
  - Starting Microlut after a miscarriage or abortion
    If you have had a miscarriage or an abortion **during the first three months of pregnancy,** your doctor may tell you to start taking Microlut straight away, in which case another method of contraception will not be required.
  - Using contraceptives after delivery
    If you have recently had a baby, your doctor will advise you to start taking Microlut immediately after delivery. If you start taking Microlut later, you will need to use another method of contraception, such as a condom, during the first 7 days of use. If you have already had intercourse, you must rule out the possibility that you are pregnant before you start taking Microlut, or wait until your next period.

If you recently had a baby and you are breastfeeding, see in section 2 "Pregnancy and breastfeeding" .

Tests and follow-up

Before commencing treatment with contraceptive pills, the doctor will ask you about your and your family's medical history, will check your blood pressure and will rule out possibility of pregnancy. There may be a need for additional tests, such as a breast examination, but only if you need to have these tests done or if you have specific suspicions.
During the course of treatment, see your doctor for periodic check-ups, including a Pap smear.
Each month, check for changes in the breasts and nipples. Tell the doctor if you notice or feel any change, such as lumps or dimples in the skin.
Microlut may affect the results of certain blood tests; therefore, if you have to undergo a blood test, always inform the doctor that you are taking Microlut.
Before surgery, confirm that the doctor knows you are taking Microlut. You may be asked to stop taking the pill 4-6 weeks before the surgery. This is to reduce the risk of blood clots (see in section 2 "The pill and blood clots"). The doctor will tell you when you can start taking the pill again.

If you accidentally take too high a dosage

It is unlikely that taking more than one pill will cause harm, but you may experience nausea, vaginal bleeding or you may not feel well. Consult the doctor if you experience any of these signs.
If you took an overdose, or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine

- **If you are less than 3 hours late,** take the tablet immediately. Keep taking the rest of the tablets at the usual time. This may mean taking two tablets in one day. Do not worry – the contraceptive efficacy of the medicine should not be reduced.
- **If you are more than 3 hours late,** or you have missed more than one tablet, the contraceptive efficacy of the medicine may be reduced.
  - Continue to take the rest of the tablets at the usual time.
  - Use an additional contraceptive method, such as a condom, for the next 7 days.

If you forgot to take tablets from a pack and had intercourse in the week before the day you forgot, there is a possibility that you are pregnant. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy of the medicine is decreased.

If you lost a pill

Choose one of the following options:
Take the last tablet of the pack in place of the tablet you lost. Continue taking the rest of the tablets on their appropriate days. When you start a new pack, the starting day will change and will be one day earlier than the previous pack.
Or, if you have an extra pack and do not want to change the starting day of your next pack, take a tablet from that extra pack. Continue taking the rest of the tablets from your current pack as usual. You can then keep the opened pack as a spare, in case you lose any more pills.

If you vomit or have diarrhea

If you vomit within two hours of taking the tablet, your body may not have absorbed the entire dose of the hormone, and you will therefore have to take another tablet as soon as possible. Follow the instructions in section "If you lost a tablet". If you are not able to take another tablet within 3 hours, use an extra contraceptive method, such as a condom, for the next 7 days.
If you are persistently sick or have severe diarrhea, use an extra contraceptive method, such as a condom, during the illness and until you recover.
Adhere to the treatment regimen recommended by the doctor.

When you want to become pregnant

If you are planning to become pregnant, it is best to use another method of contraception after stopping Microlut until you have a period. Your doctor will rely on the date of your natural period to predict the expected due date. However, it will not harm you or the baby if you get pregnant straight away.

- Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

4) SIDE EFFECTS:

As with any medicine, use of Microlut may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Severe side effects - refer to a doctor immediately if you experience any of the following signs

Signs of a blood clot:

- a migraine for the first time, or worsening of a migraine, or frequent or severe headache
- any eyesight disturbance (such as loss of vision or blurred vision)
- sudden changes in hearing, speech, sense of smell, taste or touch
- pain or swelling of the legs
- stabbing pain when breathing
- coughing for no apparent reason
- pain and tightness in the chest
- weakness or numbness in one side of the body
- dizziness or fainting

Signs of a severe allergic reaction to Microlut:

- swelling of the face, lips, mouth, tongue or throat

Signs of breast cancer include:

- dimpling of the skin
- changes in the nipple
- lumps that you see or feel

Signs of severe liver problems include:

- severe pain in your upper abdomen
- yellowing of the whites of the eyes (jaundice)
- inflammation of the liver (hepatitis)
- itching throughout the body

If any of the effects mentioned above occur, refer to the doctor immediately. The doctor may tell you to stop using Microlut.

Less serious side effects

- bleeding or spotting between periods
- absence of periods
- allergic reactions, including wheezing, rash and reddened skin
- depressive moods, loss of interest in sex
- headache or migraine
- dizziness
- nausea or vomiting
- weight gain or loss

If a side effect occurs, if one of the side effects worsens, or if you are suffering from a side effect not listed in the leaflet, consult the doctor.

If your periods seems different

A few women have irregular periods, unexpected bleeding, spotting or no periods at all while they are taking Microlut, especially during the first few months of treatment. Normally, these changes are of no concern and require no treatment. Continue taking Microlut as usual. The problem should disappear after using a few packs.
Unexpected bleeding may occur if Microlut was taken irregularly; try to take the tablet at the same time every day.
Irregular bleeding may also be caused by other medicines.

Consult the doctor in the following cases

- If you get breakthrough bleeding or spotting that:
  - carries on for more than a few months
  - began after you have been taking Microlut for a while
  - carries on even after you have stopped taking Microlut
- If you have not had a period for 6 weeks

5) HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.
- Store in the original package.
- Do not discard medicines in the waste bin. Consult the pharmacist as to how to dispose of medicines you no longer need. In this way, you will be protecting the environment.

6) FURTHER INFORMATION

- In addition to the active ingredient, this medicine also contains:
  Lactose monohydrate, maize starch, povidone 25000, talc, magnesium stearate, sucrose, povidone 700000, macrogol 6000, calcium carbonate, montanglycol wax.
  Each tablet contains 33.12 mg lactose and 19.66 mg sucrose.
- What the medicine looks like and what are the contents of the package?
  The tablets are white, round and film-coated.
  The tablets are provided in trays (blisters) in packs of 35 tablets. Each pack contains one or three blisters.
  Each tablet is labeled with a day of the week.
  Not all pack sizes may be marketed.
- Registration holder and address: Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 45240.
- Manufacturer and address: Bayer Pharma AG, Berlin, Germany.
- This leaflet was checked and approved by the Ministry of Health in April 2014.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 135 07 31197 00