Package leaflet: Information for users

Microlut® 0.03 milligram coated tablets
Levonorgestrel

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. WHAT MICROLUT IS AND WHAT IT IS USED FOR

Microlut is a hormonal contraceptive belonging to the group of the so-called minipills. In contrast to 'combined Pills' (combined oral contraceptives), that contain two hormones, an estrogen and a progestogen (gestagen), minipills contain only one progestogen, and that in a low dose.

Microlut is used for contraception.

Children
Microlut must not be used before the menarche.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MICROLUT

Do not take Microlut,

- if you are allergic to levonorgestrel or one of the other components of this pharmaceutical listed in section 6,
- if you are pregnant or suspect you are,
- if there is a blood clot in the veins, e.g. in a leg (deep venous thrombosis) or in the lungs (pulmonary embolism) (see also 'The minipill and thrombosis'),
- if arterial vascular disease is present or in history, e.g. myocardial infarction, cerebrovascular accident, ischemic heart disease (angina pectoris) (see also 'The minipill and thrombosis'),
- if you have sugar diabetes, which has caused vascular changes,
- if you now have or have a history of severe hepatic disease and your liver values have not yet returned to normal,
- if you have or have had a benign or malignant liver tumor,
- if you have or have had a sex hormone-dependent malignancy, such as breast cancer or genital cancer, or if you suspect that you have any of these diseases,
- if you have undiagnosed vaginal bleeding,

If any of the above cases occurs while you are taking Microlut, you must stop taking the drug immediately and see your doctor. In the meantime, you should use a different, non-hormonal contraceptive method. For further information, see also 'Warnings and precautions'.

Warnings and precautions
Talk to your doctor or pharmacist before taking

This section describes when you must immediately stop taking the minipill or when the reliability of the minipill might be impaired. In these cases, you are advised either not to have sexual intercourse or to use other, non-hormonal contraceptive methods, such as condoms or another barrier method. However, it is advisable not to use the calendar or temperature methods. These methods can fail, because taking the minipill alters the monthly fluctuations in body temperature and the uterine mucosa.

Like all oral contraceptives, Microlut does not offer any protection against HIV infection (AIDS) or other sexually transmitted diseases.

Medical examination/checkup

Before you start or resume taking Microlut, a full history must be taken of the diseases you and your close relatives have had, and pregnancy must be ruled out. The medical examination (including pelvis and breast) should reflect this medical history, as well as the contraindications and warnings relevant to this medicinal product. During the course of treatment, regular check-ups are recommended, the frequency and nature of which should be adapted to your individual state of health. Investigations, including your breasts (mammography), are to be conducted in line with current preventive care and according to your personal health status.

You require special medical monitoring, if

- you have only one fallopian tube, have or have had an inflammation of the fallopian tubes or a tubal (ectopic) pregnancy (see 'The minipill and tubal (ectopic) pregnancy')
- you smoke (see ‘The minipill and thrombosis'),
- you have sugar diabetes (see 'The minipill and other diseases')
- you are seriously overweight (body mass index above 30 kg/m^2; see 'The minipill and thrombosis')
- you or a close relative had a venous occlusion (at an early age) (see 'The minipill and thrombosis')
- you have high blood pressure (see ‘The minipill and other diseases’)
- breast cancer occurred in close relatives (see 'The minipill and cancer')
- you have a liver condition (see 'The minipill and cancer' and 'The minipill and other diseases')
- you have a tendency toward pigmentation spots (see ‘The minipill and other diseases’)

The minipill and thrombosis

The term thrombosis refers to the formation of a thrombus (blood clot), that is capable of blocking a blood vessel. Thromboses occur in such places as the deep veins of the lower leg (deep venous thrombosis). If one of these blood clots becomes dislodged, it can be carried through the bloodstream into the lung arteries, obstructing a blood vessel there (pulmonary embolism). Deep venous thromboses in the legs are rare. They can occur regardless of whether you are taking the minipill or not. They can also occur during pregnancy.

A thrombosis does not always heal completely and sometimes results in lasting disabilities. A thrombosis can even be fatal.

Large-scale investigations point to a correlation between the use of 'combined pills' and a more frequent occurrence of deep venous thromboses of the leg, other deep venous thromboses and pulmonary embolisms. The thrombosis risk is somewhat higher in women taking these drugs than in those women

who do not use the 'combined pill' for contraception. The significance of these findings for minipills, like Microlut, is not clear.

It is known that the risk of suffering a venous thromboembolism increases with age. Moreover, the risk increases, if you are seriously overweight (body mass index above 30 kg/m^2) or if you or a close relative of yours (sibling or parents at a relatively early age) had a venous thromboembolic disorder.

The risk of deep venous thrombosis of the leg may be temporarily enhanced if you undergo surgery, are strictly confined to bed or immobilized (e.g. if a leg is in a cast). In this event, you should inform your doctor as early as possible that you are taking the minipill. Your doctor will then advise you to stop taking the minipill several weeks prior to the operation, at the start of bed rest or immobilization. Your doctor will also tell you when you can resume taking the minipill after remobilization.

Equally, the risk of a blood clot may increase following childbirth.

A thrombosis can also occur in an artery (arterial thrombosis), e.g. in the coronary arteries or the arteries supplying the brain, and consequently result in myocardial infarction or stroke. Clinical observation studies showed very few signs of any link between the use of the minipill and an enhanced risk of suffering a myocardial infarction or stroke. Known risk factors for the occurrence of such conditions are increasing age, hypertension and smoking. The risk of suffering a stroke might be slightly higher in women with high blood pressure taking the minipill.

If high blood pressure occurs while you are taking Microlut, you might be advised to stop taking the drug and to use a different contraceptive method.

The following symptoms can be signs of venous or arterial thrombosis. If you notice any of these symptoms in yourself, stop taking the tablets immediately and see a doctor, right away:

- unusual pain or swelling in a leg,
- pain and tightness in the chest, possibly radiating into the left arm,
- sudden difficulty in breathing,
- sudden, severe coughing,
- unusual, strong or persistent headaches,
- sudden partial or complete loss of vision,
- seeing double,
- indistinct speech or problems with speaking,
- dizziness,
- collapse, possibly in connection with an epileptic seizure,
- sudden weakness or numbness on one side of the body or in one part of the body,
- problems with movement (motor disturbances),
- severe, intolerable abdominal pain.

The minipill and cancer

Breast
Breast cancer is diagnosed slightly more often in women who are currently using the 'combined pill' than in women of the same age who do not use combined oral contraceptives. It is not known, whether this is caused by the 'combined pill'. The difference may be due to the fact that women who take the 'combined pill' get examined more frequently and thoroughly, so that breast cancer is discovered earlier. The difference can also be the result of a combination of both.

Because breast cancer is rare in women under 40 years of age, the excess number of breast cancer diagnoses in current and recent users of 'combined pills' is small in relation to the overall risk of breast cancer.

This number of breast cancer diagnoses gradually levels out and after 10 years, there is no ascertainable difference between previous 'combined pill' users and other women. This risk for women taking the minipill is about the same as for those taking 'combined pills', even though the data collected for the minipill is less conclusive.

The breast cancers diagnosed in ever-users tend to be less advanced clinically than the cancers diagnosed in never-users.

Liver
In rare cases, benign liver tumors, and even more rarely, malignant liver tumors have been reported in users of 'combined pills'. In isolated cases, these tumors have led to life-threatening intra-abdominal hemorrhages. If you suddenly have severe abdominal pain, you must see your doctor, right away.

Psychiatric conditions:
Some women using hormonal contraceptives such as Microlut have reported depression or depressed mood. Depression can be serious and may occasionally lead to suicidal thoughts. If you experience mood swings or depressive symptoms, contact your doctor for further medical advice as soon as possible.

The minipill and other diseases

The minipill generally does not appear to affect blood pressure in healthy women. However, if a sustained hypertension develops during the use of Microlut, it is advisable to discontinue Microlut.

Occurrence of full-body itching (cholestatic pruritus) or blockage of bile drainage (cholestatic icterus) necessitates the discontinuation of Microlut. Particular caution is required, if these disorders have already occurred during pregnancy or previous use of hormones.

If you are diabetic, the required dose of the medicinal products used to treat your diabetes (diabetes mellitus) may change while taking Microlut. Diabetic women, also those with a history of gestational diabetes mellitus, should therefore be carefully observed while taking Microlut, especially during the initial stages of use.

Yellowish-brown pigmentation spots may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation (e.g. sun tanning equipment) while taking Microlut.

The minipill and tubal (ectopic) pregnancy

In those exceptional cases when a woman becomes pregnant while taking the minipill, the pregnancy is more likely to be tubal (ectopic) than are pregnancies among users of the 'combined pill'.

Therefore, in women with a history of tubal (ectopic) pregnancy, of ovaritis or who have only one fallopian tube, Microlut should be used only after careful risk/benefit assessment by a doctor.

If lower abdominal complaints occur together with an irregular cycle pattern (no bleeding (amenorrhea) or a stretch of time without bleeding (amenorrhea) followed by persistent bleeding), an extrauterine pregnancy must be considered. If this happens, you must see your doctor at once.

The minipill and persistent ovarian cysts

Persistent ovarian follicles (persistent follicles are often referred to as functional ovarian cysts) may occur during the use of the minipill. Most of these follicles are asymptomatic, although some may be accompanied by pelvic pain or painful sexual intercourse (dyspareunia). In most cases, the enlarged follicles disappear spontaneously during two to three months of observation.

In the following cases you should see your doctor as soon as possible

- changes in your health, e.g. occurrence of conditions described elsewhere in these instructions for use (see 'Do not take Microlut', and 'Warnings and precautions', also consider any disorders, that have occurred in your close relatives),
- lumps in the breast,
- persistent or increased irregular bleeding,
- if you forgot to take tablets or took them late and had sexual intercourse,
- if your menstrual bleeding does not occur within six weeks after your last menstrual bleeding (only start a new blister pack when it is certain that you are not pregnant),
- if you have unexplained lower abdominal complaints together with an irregular cycle pattern (menstrual bleeding does not occur (amenorrhea) or if bleeding fails to occur (amenorrhea) followed by irregular bleeding, see 'The minipill and tubal (ectopic) pregnancy'),
- if you notice possible signs of a thrombosis (see 'The minipill and thrombosis').

Reduced efficacy

The efficacy of Microlut can be impaired in the event of
- one or multiple missed or late tablets (see 'If you forget to take Microlut'),
- vomiting and/or severe diarrhea (see 'If you suffer from vomiting and/or diarrhea'),
- concomitant medication (see 'Taking Microlut with other medicines').

If Microlut and products containing St. John's wort are taken at the same time, it is advisable to use an additional barrier contraceptive method (see 'Taking Microlut with other medicines').

Reduced cycle control

- Menstrual bleeding

Menstrual bleeding occurs at normal intervals and is of normal duration and intensity in the majority of cases while taking the minipill. However, both shortened and lengthened intervals are observed.

These changes mainly occur in the initial months of use. The bleeding pattern then becomes steady during the course of further use, establishing a personal menstrual rhythm in most cases. You should always record bleeding in a calendar.

- Procedure in the event of intermenstrual bleeding

Intermenstrual bleeding of varying intensity may occur, particularly during the first few months. This is not a medical reason to stop taking Microlut. You should, however, inform your doctor so that organic causes for such bleeding can be ruled out.

- Absence of menstrual bleeding

Absence of menstrual bleeding (amenorrhea) may occur, in most cases only for one or two menstrual periods. In rare cases, bleeding may fail to occur for longer intervals.

If no menstrual bleeding has occurred within 6 weeks after the last menstrual bleeding, see your doctor so that pregnancy can be excluded before tablet taking is continued.

<u>Additional information for particular patient groups</u>
<u>Use in children and adolescents</u>

Microlut is not suited for use before the first monthly period (menarche).

Elderly women
Microlut is not suited for use after menopause.

Women with impaired liver function
Do not take Microlut if you suffer from severe liver disorders. See also sections ‘Do not take Microlut’ and 'Warnings and precautions'.

Taking Microlut with other medicines

Please inform your doctor or pharmacist if you are taking/using or have recently taken/used any other medicines or are planning to take/use any other medicines, even those not prescribed. Also inform any other doctor or dentist who prescribes you other medicines (or the pharmacist) about the fact that you are taking Microlut. They can then tell you whether you need to use additional precautionary birth control methods and, if yes, for how long.

Please note, that this information can also apply to medicines that you have used recently.

Some medicines

- may influence the blood levels of Microlut
- decrease the contraceptive efficacy of the minipill
- may result in unexpected bleeding.

Among them are:
- drugs used in treating:
  - epilepsy (e.g., primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate)
  - tuberculosis (e.g., rifampicin)
  - HIV and hepatitis C virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors)
  - fungal diseases (e.g. griseofulvin, azole antifungal drugs, e.g., fluconazole, itraconazole, ketoconazole, voriconazole)
  - bacterial infections (macrolide antibiotics, e.g., clarithromycin, erythromycin)
  - specific heart diseases, high blood pressure (calcium channel blockers, e.g., verapamil, diltiazem)
- the herbal medicine St. John’s wort (primarily used to treat depression)
- grapefruit juice.

If you need to take such drugs for longer periods, please ask your primary care physician for advice. When considered necessary, you should use a different, non-hormonal contraceptive method.

The minipill may influence the effect of other drugs. Accordingly, plasma and tissue concentrations may increase (e.g. cyclosporin, a drug used to prevent organ transplant rejections).

Note: You should refer to the instructions for use of the respective concomitant medication to identify any possible interactions.

Laboratory tests
Inform your doctor or the laboratory staff that you are taking Microlut if you have to have a blood test or other laboratory tests done as its use may influence the results of some tests.

Pregnancy and breast-feeding.

Pregnancy

If you are pregnant or breast-feeding or think you may be pregnant, you must not take Microlut. If you become pregnant whilst taking Microlut, immediately stop taking it and see your doctor.

Undesired hormonal effects on the development of genitourinary organs cannot be completely ruled out, but most of the scientific studies carried out to date have revealed neither an increased risk of birth defects in children born to women who used contraceptives prior to pregnancy, nor a teratogenic effect when progestogens have been taken inadvertently during pregnancy at doses, like those contained in Microlut.

Breast-feeding

The minipill is considered to comprise the next choice category after non-hormonal methods.

There appears to be no adverse effects on infant growth or development when using the minipill after six weeks postpartum. The minipill does not appear to affect the quantity or quality of breast milk, however, minute amounts of the active substance are excreted with the milk.

Effects on ability to drive and use machines

No special precautions are necessary.

Microlut contains sugar (sucrose) and milk sugar (lactose). Please, take Microlut only after consulting with your doctor, if you know that you suffer from an intolerance of certain sugars.

3. HOW TO TAKE MICROLUT

Always take this medicinal product exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Method of administration

This medicinal product is to be taken orally.

You should take the tablets whole (do not chew) with sufficient liquid (preferably with a glass of water).

The usual dose is

1 tablet daily.

Microlut is taken continuously, i.e. without any break.
This means that, after the first pack has been finished, the next should be started without interruption.

Microlut must be taken at the same time each day, continuously, without any break, without regard to bleeding (menstrual bleeding or even intermenstrual bleeding).

The attempt should always be made to maintain an interval of exactly 24 hours between tablets. This interval should by no means be exceeded by more than 3 hours, otherwise protection against conception may be at risk. The greatest possible reliability of Microlut can be assured only by adhering as closely as possible to the 24-hour-intervals.

When to start taking the pill from the first blister pack

If you did not take a contraceptive 'Pill' last month:
Start taking Microlut on day 1 of your natural cycle, i.e. the first day of your menstrual bleeding.

Start taking the tablets by removing the first tablet from the field of the calendar pack, marked with the abbreviated day of the week (e.g. 'Mo' for Monday). Take the rest of the pills in the direction of the arrow on the blister pack continuously for 35 days, until the blister pack has been used up. Then, start taking the tablets from the next blister pack on the very next day.

If you start taking Microlut later than on the first day of menstruation, an additional barrier method of contraception is to be used during the first seven days. If you proceed as described earlier, however, contraception is guaranteed from the start of tablet taking.

Switching from a 'combined pill', a vaginal ring or a contraceptive patch:
If you have always taken the ‘previous pill’ correctly and consistently, you should start taking Microlut immediately on the day after you take the last hormone-containing tablet (or, if you take a ‘pill’ every day, after the last hormone-containing tablet) of the 'combined pill' and thus leave out the tablet-free interval.

If the pack of the 'previous pill' also contains tablets without active substances, you must not take them.
If you are not sure what type of combined pill you have taken or which is the last hormone-containing tablet, ask your doctor or pharmacist.

If you always used a vaginal ring or contraceptive patch correctly and consistently before switching, you should start taking Microlut on the day of removal of the last vaginal ring or contraceptive patch of a cycle pack and thus omit the hormone-free interval.

If you proceed as described earlier, however, continuous contraception is guaranteed.

Switching from another minipill:
You can stop taking the previous minipill on any day you wish and start with Microlut on the very next day.
If you take the tablets correctly, it is not necessary to take any additional contraceptive measures.

Switching from an injection or implant:
Start taking Microlut at the time you would normally get the next injection or on the day the implant is removed.
When switching from an implant or injectable product, an additional barrier method of contraception must be used during the first seven days.

After childbirth:
Women who are not breastfeeding can start taking the tablets 21 days after giving birth. An additional barrier method must be used during the first seven days. If you have already had sexual intercourse, pregnancy must be ruled out or you have to wait for your first menstrual bleeding before starting to take Microlut.

After a miscarriage or an abortion:
Please, talk to your doctor about when to start taking the tablets.

Use in breastfeeding women:

(see 'Pregnancy and breastfeeding’)

If you take more Microlut than you should

There have been no reports of serious deleterious effects from taking multiple Microlut tablets. If multiple tablets are taken at once, nausea, vomiting and also slight vaginal bleeding may occur.

If you discover that a child has inadvertently taken several tablets, please see a doctor.

If you forget to take Microlut:

Even if only one tablet was taken late (i.e. if more than 27 hours have elapsed since the last tablet was taken) or if one tablet was forgotten, contraceptive protection may be impaired.

The missed tablet should be taken as soon as possible, even if this means having to take two tablets at the same time. Then, resume taking the tablets at your usual time. In addition, barrier methods have to be used for the next seven days.

If you have had sexual intercourse in the last seven days, you could be pregnant. If this happens, please see your doctor. The risk of becoming pregnant increases with the number of tablets you have forgotten.

If you suffer from vomiting and/or diarrhea

If you have to vomit within the first three to four hours of taking the tablet and/or have diarrhea, your body may not have completely absorbed the active substance. This situation is comparable to missing a tablet. If this happens, please follow the advice given in the previous section. An additional barrier method of contraception has to be used for the following seven days. Take any replacement tablet(s) from the end of the blister pack, so that you can still monitor your daily use according to the days of the week on the blister pack.

If you stop taking Microlut

You can stop taking Microlut at any time. If you do not want to become pregnant, ask your doctor about other reliable contraceptive methods.

If you have any further questions on the use of this product, refer to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this pharmaceutical medicine can cause undesirable effects, although not everybody gets them.

The following side effects have been reported following the use of Microlut:

Very common (more than 1 in 10 users can be affected):
Bleeding disturbances, such as spotting, intermenstrual bleeding or absence of menstrual bleeding

Common (1 in 10 users can be affected):
Depressed mood, libido decreased, libido increased, headaches, dizziness, nervousness, nausea, vomiting, acne, breast pain, breast tension, painful menstruation, vaginal inflammation, prolonged menstrual bleeding*, prolonged intermenstrual bleeding*

Uncommon (1 in 100 users can be affected):
Yellowish-brown pigmentation spots (Chloasma), fluid retention in tissue

Rare (1 in 1000 users can be affected):

Hypersensitivity reactions, contact lens intolerance, excess male pattern hair growth (Hirsutism), skin conditions *, changes in vaginal discharge, weight increased, weight decreased.

(* generally applies to progesterone-only products)

As regards other severe undesirable effects, such as the formation of blood clots, liver tumors, breast and cervical cancer, see 'Warnings and precautions'.

Ectopic pregnancies are more likely to occur among users of the minipill than among users of combined oral contraceptives (see also 'The minipill and tubal (ectopic) pregnancy'). Persistent ovarian follicles (functional ovarian cysts) may occur during the use of Microlut (see also 'The minipill and persistent ovarian cysts').

Reporting side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. By reporting side effects, you can contribute to making more information about the safety of this medicine available.

5. HOW TO STORE MICROLUT

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the folding carton and on the blister.

Storage conditions

Store below 30 °C

6. Contents of the pack and other information

What Mircrolut contains:

The active substance is levonorgestrel

One coated tablet contains 0.03 mg levonorgestrel.

The other ingredient(s) are:
Lactose monohydrate, maize starch, polyvidone 25,000, talcum, magnesium stearate (Ph.Eur.), sucrose (saccharose), polyvidone 90,000, macrogol 6,000, calcium carbonate, glycol montanite.

What Microlut looks like and contents of the pack

Microlut is available in packs of
1 blister pack with 35 coated tablets and
3 blister packs with each 35 coated tablets.

Not all pack sizes may be marketed.

Manufacturer
Bayer AG
Müllerstrasse 178
13353 Berlin, Germany.

Marketing Authorisation Holder
Bayer AG
Kaiser-Wilhelm-Allee 1
51368 Leverkusen, Germany.

This patient information leaflet was last revised in January 2021.

This is a medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists