

## Consumer Medicine Information

# MICROLUT<sup>®</sup>

*Levonorgestrel 30 µg tablets*

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### What is in this leaflet

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Please read this leaflet carefully before you start using MICROLUT. It will advise you about how to take MICROLUT properly and when to tell your doctor about health-related conditions. If you have any questions or need more advice, ask your doctor, professional health care provider or pharmacist.

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### What is MICROLUT used for and how does it work

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MICROLUT contains the oral progestogen levonorgestrel in a very low dose. Such progestogen-only preparations for contraception are also called the "Minipill". The pregnancy rate of progestogen-only contraceptives such as MICROLUT is slightly higher than that of combined progestogen-estrogen contraceptives (the combined "Pill"). However, MICROLUT offers a high degree of reliability when taken correctly and the chance of becoming pregnant is very low.

#### How does MICROLUT work?

The continuous daily intake of one MICROLUT tablet prevents pregnancy in several different ways. These include changes in the cervical mucus, which makes the migration and ascent of sperm difficult and changes to the lining of the womb. The release of eggs is not inhibited by MICROLUT in the majority of women, but MICROLUT has an influence on the hormonal regulation circuit, which may contribute to the contraceptive action.

#### What is MICROLUT used for?

MICROLUT is used as an oral contraceptive.

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### Before you use MICROLUT

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Do not use MICROLUT if you have any of the conditions listed below. If any of these apply to you, tell your doctor before starting to use MICROLUT. Your doctor may advise you to use a different type of hormonal contraception or an entirely different (non-hormonal) method of birth control.

#### You must not use MICROLUT if:

- you have a disorder affecting the blood circulation, in particular those conditions relating to thrombosis. Thrombosis is the formation of a blood clot. This may occur in the blood vessels of the legs (deep vein thrombosis), the lungs (pulmonary embolism), the heart (heart attack), the brain (stroke), or other parts of the body
- you have or have ever had a condition that may be a first sign of a heart attack (such as angina pectoris or chest pain) or stroke (such as transient ischaemic attack or small reversible stroke)

- you have or have had a severe liver disease and your liver function values have not returned to normal (symptoms of liver disease include yellowing of the skin and/or itching of the whole body)
- you have diabetes mellitus with blood vessel damage
- you have high blood levels of cholesterol or triglycerides (fatty substances)
- you have or have had cancer of the breast or the genital organs
- you have or have had a benign or malignant liver tumour
- you have any unexplained vaginal bleeding
- you are pregnant or think you might be pregnant
- you have had a previous ectopic pregnancy
- you are allergic to any of the ingredients of MICROLUT

If any of these conditions appear for the first time while using MICROLUT, stop taking it at once and consult your doctor. In the meantime, use non-hormonal contraceptive measures.

### **Tell your doctor if:**

If MICROLUT is used in the presence of any of the conditions listed below or they appear for the first time or recur or worsen during treatment, you may need to be kept under close observation. Your doctor can explain this to you. You should tell your doctor if:

- you smoke
- you have diabetes
- you are overweight
- you have high blood pressure
- anyone in your immediate family has had thrombosis, a heart attack or a stroke
- anyone in your immediate family has had breast cancer
- you have liver disease
- you suffer from migraine
- you suffer from epilepsy
- you have ovarian cysts
- you have fibroids
- you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet radiation

### **What else you should know**

**MICROLUT does not protect against HIV infection (AIDS) or any other sexually transmitted infections.**

In this leaflet, several situations are described where you should stop taking MICROLUT, or where the reliability of MICROLUT may be decreased. In such situations you should not have sex or you should take extra non-hormonal contraceptive precautions, e.g., use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because MICROLUT alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

- **MICROLUT and thrombosis**

Thrombosis is the formation of a blood clot which may block a blood vessel.

Thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this blood clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called "pulmonary embolism". Deep venous thrombosis is a rare occurrence. The risk of venous thromboembolism (deep venous thrombosis, pulmonary embolism) appears to be slightly higher in Minipill users than in non-users, but not as high as during pregnancy or during use of the (combined) Pill.

Blood clots can also occur very rarely in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke). Extremely rarely, blood clots can occur in the liver, gut, kidney or eye. Very occasionally a thrombosis may cause serious permanent disability, and may even be fatal.

The risk of having a heart attack or stroke increases as you get older. It also increases the more you smoke.

It is also generally accepted that the risk for venous thromboembolism increases with increasing age and increases if you are overweight and if you or anyone in your immediate family has had a thrombosis at a relatively early age.

The risk of thromboembolism is also increased shortly after childbirth.

The risk of having deep venous thrombosis is temporarily increased as a result of an operation or immobilisation (for example, when you have your leg or legs in plaster or splints). In women who use the Pill (such as MICROLUT) the risk may be even higher. Tell your doctor you are using MICROLUT well in advance of any expected hospitalisation or surgery. Your doctor may tell you to stop taking MICROLUT several weeks before surgery or at the time of immobilisation. Your doctor will also tell you when you can start taking MICROLUT again after you are back on your feet.

- **MICROLUT and cancer**

The following findings from the combined Pill may also hold true for MICROLUT users, although the evidence is not as strong for the Minipill compared to the Pill.

Breast cancer has been diagnosed slightly more often in women who use the Pill than in women of the same age who do not use the Pill. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after stopping use of the Pill. It is not known whether the difference is caused by the Pill. It may be that the women were examined more often, so that the breast cancer was noticed earlier.

In rare cases, benign, and even more rarely, malignant liver tumours have been reported in users of the Pill. These tumours may lead to internal bleeding. Contact your doctor immediately if you have severe pain in your abdomen.

Cervical cancer has been reported to occur more often in women using the Pill for a long time. This finding may not be caused by the Pill but may be related to sexual behaviour and other factors.

- **MICROLUT and other conditions**

If you develop high blood pressure while using MICROLUT, you may be told to stop using it.

If, in exceptional cases, pregnancy occurs while taking MICROLUT, there is a higher likelihood of an ectopic pregnancy (a pregnancy occurring outside the uterus) compared to the combined Pill. If you experience unexplained pain in the lower part of your abdomen together with an irregular cycle pattern (no monthly bleeding or no monthly bleeding followed by persistent bleeding), you should contact your doctor immediately because an ectopic pregnancy must be considered.

Persistent ovarian follicles (often referred to as "functional ovarian cysts") may occur during the use of MICROLUT. Most of these follicles are not combined with any symptoms, although some may be accompanied by pelvic pain or painful sexual intercourse. In this case inform your doctor. In most cases, the enlarged follicles disappear spontaneously during 2 - 3 months of observation.

Microlut contains lactose. If you have an intolerance to some sugars, contact your doctor before you start taking Microlut.

- **MICROLUT and other medicines**

Some oral medicines may stop MICROLUT from working properly. These include:

- medicines used to treat tuberculosis such as rifampicin, rifabutin
- a class of antibiotics known as macrolides, such as clarithromycin, erythromycin
- medicines used to treat fungal infections, such as ketoconazole, griseofulvin
- medicines used to treat HIV, such as ritonavir, nevirapine
- some medicines used to treat Hepatitis C Virus (HCV), such as boceprevir, telaprevir
- medicines used to treat epilepsy such as phenytoin, primidone, barbiturates (e.g. phenobarbitone), carbamazepine, oxcarbazepine, topiramate, felbamate
- cyclosporin, an immunosuppressant medicine
- some medicines used to treat high blood pressure, chest pain or irregular heartbeats such as diltiazem, verapamil
- herbal medicines containing St John's Wort
- grapefruit juice.

Always tell the doctor who prescribes MICROLUT which medicines you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the dispensing pharmacist) that you use MICROLUT. They can tell you if you need to take additional contraceptive precautions and if so, for how long.

- **MICROLUT and breast-feeding**

Hormonal contraceptives such as MICROLUT are not recommended as the contraceptive method of first choice during lactation. However, MICROLUT is often considered as the next choice. There appear to be no adverse effects on infant growth or development if MICROLUT is started six weeks after childbirth. MICROLUT does not appear to affect the quantity or quality of breast milk, however very small amounts of the hormone can be found in the breast milk.

- **MICROLUT and pregnancy**

MICROLUT must not be used by women who are pregnant, or who think they may be pregnant.

- **MICROLUT and children**

Microlut is not intended for use in females whose periods have not yet started.

- **MICROLUT and ability to drive**

There are no observed effects.

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## **How to use MICROLUT properly**

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The contraceptive protection provided by MICROLUT is continuous. Additional contraceptive precautions are only required when special circumstances (e.g. failing to take your tablet at the usual time) reduce the reliability of the preparation.

Remember that MICROLUT has been prescribed for you personally. Do not share it with others.

### **When and how to take the tablets**

The MICROLUT pack contains 28 small round white hormonal tablets. On the pack each tablet is marked with the day of the week on which it is to be taken. Take your tablet at the same time each day, with some water if necessary. Follow the direction of the arrows until all the tablets have been taken. Start your next pack on the very next day as MICROLUT is taken continuously without any break.

You should always try to maintain an interval of exactly 24 hours between tablets. This interval should not be exceeded by more than 3 hours. For example, if you choose 7 a.m. as the time for taking your tablets, you should try to always take them at this time. Whenever this is impossible, the tablet must be taken by 10 a.m. at the very latest, otherwise you may not be protected against conception. The greatest possible reliability of MICROLUT can be assured only by adhering as closely as possible to the 24-hour intervals.

### **Starting your first pack of MICROLUT**

#### **When no hormonal contraceptive has been used in the past month**

Start taking MICROLUT on the first day of your cycle, i.e. the first day of menstrual bleeding.

#### **When changing from a combined Pill**

You should start taking MICROLUT immediately on the day after the last hormonal tablet from your present Pill pack (this means no tablet-free break).

#### **When changing from another progestogen-only Pill (Minipill)**

When switching from another Minipill, you may start with MICROLUT on any day, without a break between the tablets. If you are not sure about the type of Pill you have used, contact your doctor or pharmacist.

#### **When changing from an injectable or implant**

If you have used a progestogen-only implant or injections to prevent pregnancy, you may switch from an implant on the day of its removal or from an injectable when the next injection

would be due. In both cases you should use a barrier method for the first 7 days of tablet taking.

### **After having a baby**

If you are breast-feeding, please read the section on MICROLUT and breast-feeding.

If you are not breast-feeding, you should start in the fourth week after delivery. When starting later, you may either wait for your first menstrual period or you may start straight away provided you use a barrier method for the first 7 days of tablet taking. However, if you have already had intercourse, the possibility of pregnancy should be excluded before starting MICROLUT.

### **After a miscarriage or an abortion**

You may start immediately.

### **Special circumstances**

The following describes special circumstances that could alter the way you take MICROLUT. In all situations where the reliability of MICROLUT is reduced (such as missing tablets), additional contraceptive precautions are required following the advice given below. This advice should also be followed in situations where other medicines may stop MICROLUT from working properly and in the case of vomiting or diarrhoea after taking MICROLUT.

### **If you forget to take your tablets**

If you forget to take your tablets at the usual time, follow the instructions below. This is often called the "*7 day rule*". This advice should also be followed in situations where other medicines may stop MICROLUT from working properly and in the case of vomiting or diarrhoea after taking MICROLUT.

### **Extra contraceptive precautions**

When you need extra contraceptive precautions, either:

- don't have sex; or
- use a cap plus spermicide; or
- use a condom

Do not use the rhythm or temperature methods as extra contraceptive precautions. This is because oral contraceptives alter the usual menstrual cycle changes, such as changes in temperature and cervical mucus.

#### *The 7 day rule*

- Continue taking your tablets
- You will not be protected from pregnancy until you have taken your daily small hormone tablet for the next 7 days in a row
- Use another method of contraception (*Extra contraceptive precautions*) such as condoms or do not have sexual intercourse for the next 7 days while taking the next 7 small hormone tablets

If even one tablet is taken late (i.e. it is more than 27 hours since the last tablet was taken), protection against contraception may be impaired. You should take the last missed tablet as soon as you remember, even if this means taking 2 tablets at the same time. Then continue to take tablets at your usual time. In addition, a barrier method should be used for the next 7 days. If intercourse took place in the preceding 7 days, the possibility of a pregnancy should be considered and you should contact your doctor. The more tablets you miss, the higher the risk of a pregnancy.

## **The pattern of menstrual bleeding with MICROLUT**

- **Menstrual bleeding**

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

The changes occur mainly during the first few months of use, but with continuing treatment the cycle pattern tends to stabilise, and in most cases an individual pattern is established. Keep a record of bleeding on the calendar contained in each pack.

- **Procedure in the event of intermenstrual bleeding**

Intermenstrual bleeding of varying intensity may occur, particularly during the first few months. Normally, MICROLUT does not need to be withdrawn in such cases but you should inform your doctor in any case because it may be necessary to rule out other potential causes.

- **Absence of withdrawal bleeding**

It may happen that your monthly bleeding does not occur, in most cases only for one or two menstrual periods. In rare cases bleeding may fail to occur for prolonged periods of time.

If no menstrual bleeding has occurred within 6 weeks after the last menstrual bleeding, you need to contact your doctor to have the possibility of pregnancy excluded before going on to the next pack of MICROLUT.

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## **Overdosage**

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There have been no reports of serious harmful effects from taking too many MICROLUT tablets at one time. If you have taken several tablets at a time, you may have nausea, vomiting or vaginal bleeding. If you discover that a child has taken MICROLUT, ask your doctor for advice.

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## **When using MICROLUT**

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### **Tell your doctor immediately if:**

**You should stop treatment and see your doctor immediately if you get a blood clot while you are taking MICROLUT. Warning signs to look out for are:**

- an unusual cough
- severe pain in the chest which may reach the left arm

- breathlessness
- any unusual, severe or prolonged headache or migraine attack
- partial or complete loss of vision, or double vision
- slurring or speech disability
- sudden changes to your hearing, sense of smell, or taste
- dizziness or fainting
- weakness or numbness in any part of your body
- severe pain in your abdomen
- severe pain or swelling in either of your legs

## **Tell your doctor if:**

### **Contact your doctor as soon as possible if:**

- you notice any changes in your own health, especially involving any of the items mentioned in this leaflet; do not forget about the items related to your immediate family
- you feel a lump in your breast
- you are going to use other medications
- you are to be immobilised or are to have surgery (consult your doctor at least four weeks in advance)
- you have unusually heavy or unexplained vaginal bleeding
- you miss your period within 6 weeks after the last menstrual bleeding or suspect you are pregnant (do not start the next pack until told to by your doctor).
- you experience unexplained pain in the lower part of your abdomen together with an irregular cycle pattern (no monthly bleeding or no monthly bleeding followed by persistent bleeding). You should contact your doctor **immediately** because an ectopic pregnancy must be considered.

## **Regular check-ups**

When you are using MICROLUT, your doctor will tell you to return for regular check-ups. In general, you should have a check-up every year.

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## **Side effects**

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Tell your doctor if you notice any unwanted effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by MICROLUT.

### **Serious side effects**

Serious reactions associated with the use of oral contraceptives such as MICROLUT, as well as the related symptoms, are described in the section "Before you use MICROLUT". Please read this section carefully and consult your doctor where appropriate.

### **Other possible side effects**

The following have been reported in users of the Minipill such as MICROLUT, although they may not be caused by the Minipill. Such undesirable effects that occur in the first few months that you are using MICROLUT will probably lessen with time.

- menstrual disturbances (frequent and/or irregular bleeding or no bleeding)

- breast tenderness
- headache
- dizziness
- changes in sexual drive; depressive moods
- contact lens intolerance
- nausea or vomiting
- changes in vaginal secretion
- various skin reactions (including acne or hair growth)
- changes in body weight
- hypersensitivity reactions

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## Storage

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Do not use after the expiry date stated on the package.

Store all drugs properly and keep them out of reach of children.

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## Further information

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### **MICROLUT tablets contain:**

*active substances (per tablet)*

levonorgestrel (30 micrograms)

*other substances*

Calcium carbonate, glycol montanate, lactose monohydrate, macrogol 6000, magnesium stearate, maize starch, povidone, purified talc, sucrose.

**If you have any further questions please consult your doctor or pharmacist.**

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## Name and Address

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## Date of Preparation

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