

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Microlut?

Microlut contains the active ingredient levonorgestrel. Microlut is used to prevent pregnancy.

For more information, see Section [1. Why am I using Microlut?](#) in the full CMI.

2. What should I know before I use Microlut?

Do not use if you have ever had an allergic reaction to Microlut or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Microlut?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Microlut and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Microlut?

- Take one tablet daily at the same time every day. You must take Microlut every day regardless of how often you have sex.
- An interval of exactly 24 hours should be maintained between tablets. This interval must not be exceeded by more than 3 hours.
- Swallow the tablet whole with water. It does not matter if you take it before or after food.

More instructions can be found in Section [4. How do I use Microlut?](#) in the full CMI.

5. What should I know while using Microlut?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Microlut.• If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.• Have regular check-ups with your doctor. When you are taking Microlut, your doctor will tell you to return for regular check-ups, including getting a Pap smear test.
Things you should not do	<ul style="list-style-type: none">• Do not take Microlut to treat any other conditions, unless your doctor tells you to.• Do not give your medicine to anyone else.• Do not stop taking your medicine or change the dosage without checking with your doctor.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the pack they may not keep well.• Keep your tablets in a cool dry place where the temperature stays below 30°C.

For more information, see Section [5. What should I know while using Microlut?](#) in the full CMI.

6. Are there any side effects?

Common side effects: nausea; vomiting; stomach pain together with bleeding irregularities including more frequent, less frequent or no bleeding; headache, including migraines; dizziness; mood changes, including depression; breast tenderness or pain.

Serious side effects: Blood clots, jaundice (yellowing skin or yellowing eyes), you cough up blood, breast lumps, unexplained lower abdominal pain, including loss of periods or heavy bleeding, unexplained vaginal bleeding.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Active ingredient(s): *levonorgestrel*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Microlut. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Microlut.**

Where to find information in this leaflet:

- [1. Why am I using Microlut?](#)
- [2. What should I know before I use Microlut?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Microlut?](#)
- [5. What should I know while using Microlut?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Microlut?

Microlut contains the active ingredient levonorgestrel.

Microlut is an oral progestogen-only contraceptive, commonly known as the 'Mini-pill'.

Microlut is used to prevent pregnancy.

When taken correctly, it prevents you from becoming pregnant in several ways, including:

- changing the cervical mucus consistency, making it more difficult for the sperm to reach the egg
- changing the lining of the uterus, making it less suitable for implantation
- impairing mid-cycle functions, which may contribute to contraceptive action.

Like all oral contraceptives (OC), Microlut is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted infections.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I use Microlut?

Warnings

Do not use Microlut if:

- you are allergic to levonorgestrel, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- you have or have had a blood clot in:

- the blood vessels of the legs (deep vein thrombosis - DVT)
- the lungs (pulmonary embolism - PE)
- the heart (heart attack)
- the brain (stroke)
- other parts of the body

- **you are concerned about an increased risk of blood clots.** Blood clots are rare. Very occasionally blood clots may cause serious permanent disability, and may even be fatal.

You are more at risk of having a blood clot when you take the Mini-pill. However, the risk of having a blood clot when taking the Mini-pill is less than the risk of having a blood clot during pregnancy.

- **you are concerned about an increased risk of blood clots because of age or smoking.** The risk of having a heart attack or stroke increases as you get older. It also increases if you smoke. You should stop smoking when taking the Mini-pill, especially if you are older than 35 years of age.
- you have, or have had diabetes mellitus with blood vessel damage.
- you have, or have had severe liver disease and your liver function has not returned to normal.
- you have, or have had cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs).
- you have, or have had benign or malignant liver tumour.
- you have, or have had unexplained vaginal bleeding.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- smoke
- have abdominal pain with infrequent and/or irregular periods
- have ever had an extra uterine/ectopic pregnancy (where an embryo has developed outside the womb) or an impairment in your fallopian tube function (e.g. caused by inflammation)
- or anyone in your immediate family has had blood clots in the legs (DVT) or lungs (PE), a heart attack, a stroke, breast cancer or high cholesterol
- have, or have had diabetes
- have, or have had high blood pressure
- have, or have had kidney or heart problems
- have, or have had migraine
- have, or have had asthma
- have, or have had epilepsy
- have, or have had depression
- are overweight
- have high cholesterol or triglycerides
- have liver disease
- have gall bladder disease

- have a condition that occurred for the first time, or worsened during pregnancy or previous use of sex hormones (e.g. cholestatic jaundice and/or pruritis (itching))
- have chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face) – if so, avoid exposure to the sun or ultraviolet radiation
- if you have an intolerance to some sugars. Microlut contains lactose.

If any of the above conditions appear for the first time, recur or worsen while taking Microlut, you should contact your doctor.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant or think you might be pregnant.

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

Children under 18 years old

- Do not give this medicine to a child. Microlut is not intended for use in females whose periods have not yet started.

3. What if I am taking other medicines?

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

Some medicines may interfere with Microlut and affect how it works.

- 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, lamotrigine
- antibiotics (e.g. penicillins, nitrofurantoin, tetracycline)
- 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.

These medicines may be affected by Microlut, or may affect how well it works. Your doctor may need to alter the dose of your medicine, or prescribe a different medicine.

You may need to use additional barrier methods of contraception (such as condoms or a diaphragm) while you are taking any of these medicines and for some time after stopping them. Your doctor will be able to advise you on how long you will need to use additional contraceptive methods.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Microlut.

4. How do I use Microlut?

How much to take / use

- Take one tablet daily at the same time every day. You must take Microlut every day regardless of how often you have sex. This will also help you remember when to take it.
- An interval of exactly 24 hours should be maintained between tablets. This interval must not be exceeded by more than 3 hours. Even if one tablet is taken late (i.e. more than 3 hours later than when it should have been taken) or if one tablet is missed altogether, protection against pregnancy may be impaired.
- Swallow the tablet whole with water. It does not matter if you take it before or after food.
- Each blister pack is marked with the day of the week. Take your first tablet from the blister pack corresponding to the day of the week.
- Follow the direction of the arrows on the blister pack until all the tablets have been taken. Each blister pack is marked with the day of the week.
- Tablets must be taken for 28 consecutive days. There is no break between packs. This means that when the first pack is finished the next should be started without interruption.
- If you do not understand the instructions on the blister pack, ask your doctor or pharmacist for help.
- Always start a new blister pack on the same day of the week as your previous pack.
- Follow the instructions provided and use Microlut until your doctor tells you to stop.

When to take / use Microlut

Taking Microlut for the first time

If you are starting Microlut after a natural cycle, and you have not used a hormonal contraceptive in the past month, start on the first day of your period, i.e. on the first day of your menstrual bleeding.

Your doctor will advise you when to start if you:

- are taking Microlut after having a baby

- are breast-feeding
- have had a miscarriage or an abortion

Changing from a combined oral contraceptive

Start taking Microlut on the day after taking the last active tablet in your previous pill pack. Do not take the inactive (sugar) tablets of your previous pack.

If you are not sure which were active/inactive tablets in your previous pill pack, ask your doctor or pharmacist. Your previous pill pack may have different colour tablets to those of Microlut.

Changing from a progestogen-only pill ('Mini-pill')

Stop taking the previous Mini-pill on any day and start taking Microlut at the same time the next day, without any break between Mini-pills.

Changing from a progesterone-only injection or implant

Start taking Microlut when your next injection is due, or on the day that your implant is removed.

You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 7 days of tablet-taking when having intercourse.

Stopping Microlut

You can stop taking Microlut at any time. If you are considering becoming pregnant, it is recommended that you begin taking a vitamin supplement containing folic acid. It is best that you start taking folic acid tablets before you stop taking Microlut and not stop until your doctor advises this. Seek advice from your doctor or pharmacist about suitable supplements. It is both safe and recommended that you take folic acid during pregnancy.

Additional contraceptive precautions

When additional contraceptive precautions are required you should either abstain from sex, or use a barrier method of contraception, a cap (or diaphragm) plus spermicide, or a condom. Rhythm methods are not advised as Microlut disrupts the cyclical changes associated with the natural menstrual cycle e.g. changes in temperature and cervical mucus.

If you forget to use Microlut

Microlut should be used regularly at the same time each day. If you miss your dose at the usual time, take the missed tablet as soon as you remember, even if this means taking two tablets at the same time. Then continue to take your tablets at the usual time.

In addition, you should also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the next 7 days.

If you have had sexual intercourse in the week before, taking your tablet(s) late or missed a tablet(s), there is a high possibility of becoming pregnant. **Seek advice from your doctor or pharmacist about what to do.**

Please refer to the table at the end of this leaflet ["Summary of advice when late taking or missing a Mini-pill"](#).

If you use too much Microlut

If you think that you have used too much Microlut, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26** in Australia or **0800 764 766** in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Microlut?

Things you should do

- If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.
- Have regular check-ups with your doctor. When you are taking Microlut, your doctor will tell you to return for regular check-ups, including getting a Pap smear test. Your doctor will advise how often you need a Pap smear test. A Pap smear test can detect abnormal cells lining the cervix. Sometimes abnormal cells can progress to cancer.

Stop taking Microlut and call your doctor straight away if you notice possible signs of thrombosis:

- an unusual cough
- severe pain or heaviness in the chest
- 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, swelling or discolouration in either of your legs.

Surgery

If you are going to have surgery, tell the surgeon or anaesthetist beforehand that you are taking Microlut. The risk of having DVT is temporarily increased as a result of an

operation or immobilisation (for example, when you have your leg(s) in plaster/splints). In women who take the Mini-pill, the risk may be higher.

Your doctor may tell you to stop taking the Mini-pill several weeks before surgery, or at the time of immobilisation, and when you can start taking the Mini-pill again. If you notice possible signs of a thrombosis, stop taking the Mini-pill and consult your doctor immediately.

High blood pressure

Consult your doctor if you develop high blood pressure while taking Microlut – you may be told to stop taking it.

Pregnancy

If you become pregnant while taking this medicine, tell your doctor immediately.

Vomiting

If you vomit within 3-4 hours or have severe diarrhoea after taking a tablet, the active ingredients may not have been completely absorbed. This is like missing a tablet. Follow the advice for missed tablets.

Unexpected bleeding

If you have unexpected bleeding and it continues, becomes heavy, or occurs again, tell your doctor.

When taking these tablets for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection, but continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to the Mini-pill, usually after about 3 months.

Period

If you have missed a period, but you have taken all your tablets, it is unlikely that you are pregnant as long as:

- you have taken the tablets at the right time
- you have not been taking a medicine(s) that may interfere with your Mini-pill
- you have not vomited or had severe diarrhoea during this cycle.

If this is so, continue to take Microlut as usual. If you have any concerns consult your doctor or pharmacist.

If you miss your period twice in a row, you may be pregnant even if you have taken Microlut correctly. Stop taking Microlut and seek advice from your doctor. You must use a non-hormonal method of contraception (such as condoms, or a diaphragm) until your doctor rules out pregnancy.

Sexually transmitted infection (STIs)

Microlut will not protect you from HIV-AIDS or any other STIs, such as chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, human papillomavirus and syphilis.

To protect yourself from STIs, you will need to use additional barrier contraceptives (e.g. condoms).

Remind any doctor, dentist or pharmacist you visit that you are using Microlut.

Things you should not do

- Do not take Microlut to treat any other conditions, unless your doctor tells you to.
- Do not give your medicine to anyone else.
- Do not stop taking your medicine or change the dosage without checking with your doctor.
You may become pregnant if you are not using any other contraceptive and you stop taking Microlut, or do not take a tablet every day.
- Do not take this medicine if the packaging is torn or shows signs of tampering.
If the packaging is damaged, return it to your pharmacist for disposal.

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the pack they may not keep well.
- Keep your tablets in a cool dry place where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal: <ul style="list-style-type: none">• nausea, vomiting Reproductive system and breast-	Speak to your doctor if you have any of these less serious side

related: <ul style="list-style-type: none"> • stomach pain together with bleeding irregularities including more frequent, less frequent or no bleeding • breast tenderness or pain. Nervous system: <ul style="list-style-type: none"> • headache, including migraines • dizziness Mood-related: <ul style="list-style-type: none"> • mood changes, including depression 	effects and they worry you.
--	------------------------------------

Serious side effects

Serious side effects	What to do
Blood-clot related: <ul style="list-style-type: none"> • pain in the chest, arm or below the breastbone • discomfort radiating to the back • breathlessness and/or difficulty breathing • swelling, pain or tenderness in one leg • sudden weakness, numbness or bad ‘pins and needles’ of the face, arm or leg, especially on one side of the body • sudden trouble walking, dizziness, loss of balance or coordination • severe, sudden stomach pains • a fainting attack, or you collapse • unusual headaches or migraines that are worse than usual • sudden problems with speech, understanding or eyesight <p>You cough up blood</p> <p>Jaundice (yellowing skin or yellowing eyes)</p> <p>Reproductive system and breast-related:</p> <ul style="list-style-type: none"> • breast lumps • unexplained lower abdominal pain, including loss of periods or heavy bleeding. In rare cases pregnancies may occur during use of the Mini-pill. These pregnancies are more likely to be extrauterine/ectopic (where the embryo grows outside of the womb). • unexplained vaginal bleeding 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Thrombosis and the Mini-pill

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

Thrombosis sometimes occurs in the deep veins of the legs (DVT). If a blood clot breaks away from the veins where it has formed, it may reach and block the arteries of the lungs, causing pulmonary embolism (PE).

Blood clots can also occur in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke).

Blood clots are a rare occurrence and can develop whether or not you are taking the Mini-pill. They can also happen during pregnancy. The risk of having blood clots is higher in Mini-pill users than in non-users, but not as high as during pregnancy.

The risk of a blood clot is highest during the first year of taking the Mini-pill for the first time, or after having a break from the Mini-pill for 4 weeks or more.

If you notice possible signs of a blood clot, stop taking Microlut and consult your doctor immediately.

If you are concerned about an increased risk of blood clots while on Microlut, speak to your doctor.

Cancer and the Mini-pill

Breast cancer has been diagnosed slightly more often in women who use oral contraception than in women of the same age who do not. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after women stop taking the Mini-pill.

It is not known whether the difference is caused by the Mini-pill. It may be that these women were examined more often, so that the breast cancer was noticed earlier.

It is important that you check your breasts regularly and contact your doctor if you feel any lump.

In rare cases benign liver tumours and, even more rarely, malignant liver tumours have been reported in users of the Mini-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 who have been taking the Mini-pill for a long time. This finding may not be caused by the Mini-pill, but may be related to sexual behaviour and other factors.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems (Australia) or <https://pophealth.my.site.com/carmreportnz/s/> (New Zealand). By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Microlut contains

Active ingredient (main ingredient)	30 micrograms of levonorgestrel
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• calcium carbonate• glycol montanate• lactose monohydrate• macrogol 6000• magnesium stearate• maize starch• povidone• purified talc• sucrose
Potential allergens	Lactose monohydrate. Microlut tablets do not contain gluten. Tablets also do not contain tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What Microlut looks like

Microlut comes in a box containing 1 or 4 blister packs (AUST R 10696).

Each blister pack contains 28 white active tablets.

Not all pack sizes may be marketed.

Who distributes Microlut

Made in Germany for:

Bayer Australia Ltd

ABN 22 000 138 714

875 Pacific Highway

Pymble NSW 2073

Bayer New Zealand Ltd

PO Box 2825

Shortland Street

Auckland 1140

New Zealand

See TGA website (www.ebs.tga.gov.au) in Australia or Medsafe website (www.medsafe.govt.nz) in New Zealand for latest Consumer Medicine Information.

® Registered Trademark of the Bayer Group, Germany

© Bayer Australia Ltd

All rights reserved.

This leaflet was prepared in June 2025.

SUMMARY OF ADVICE WHEN LATE TAKING *OR* MISSING A MINI-PILL

If it has been more than 27 hours since your last tablet was taken <u>or</u> you have missed a tablet, then:	<ul style="list-style-type: none">• Take the tablet you missed even if this means taking two at the same time. Use barrier contraception for the next 7 days.• Continue taking tablets at usual time.	<ul style="list-style-type: none">• If you had sex in the 7 days prior to taking your late tablet or missed tablet, the risk of pregnancy is increased.• Contact your doctor or pharmacist for advice
---	--	--