

PRIMOLUT® N

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 taking PRIMOLUT N?

PRIMOLUT N contains the active ingredient norethisterone. PRIMOLUT N is used to treat: irregular menstrual periods with heavy and/or persistent bleeding that has no identified cause; lack of menstrual bleeding; premenstrual complaints (premenstrual syndrome); menopausal complaints in combination with estrogen as part of hormone replacement therapy; endometriosis (a disease caused by womb-lining tissue growing outside the womb).

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

2. What should I know before I take PRIMOLUT N?

Do not use if you have ever had an allergic reaction to norethisterone 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 take PRIMOLUT N?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PRIMOLUT N 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 take PRIMOLUT N?

- Your doctor will advise you about how many tablets to take but this can vary from 1 to 4 tablets daily depending on the condition being treated.
- Swallow each tablet whole with a glass of water. It does not matter if you take the tablets before or after food.

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

5. What should I know while taking PRIMOLUT N?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist or surgeon and anaesthetist (if having surgery) you visit that you are taking PRIMOLUT N.• Monitor for potential signs of blood clots and situations such as surgery or immobilisation (including air travel greater than 4 hours) that might increase the risk of blood clots.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine or change the dosage without checking with your doctor.• Do not take to treat other conditions unless advised by your doctor.
Driving or using machines	<ul style="list-style-type: none">• Adverse effects of PRIMOLUT N include visual disturbances, dizziness and somnolence, which could affect a person's ability to drive or use machines.
Drinking alcohol	<ul style="list-style-type: none">• n/a
Looking after your medicine	<ul style="list-style-type: none">• 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 taking PRIMOLUT N?](#) in the full CMI.

6. Are there any side effects?

Common side effects include nausea, headache (including migraines), fluid retention, shortness of breath, hypersensitivity reactions (e.g. rash, hives), abnormal vision. Serious side effects include severe allergy like reactions characterized by difficulty breathing, swollen tongue, feeling of tightness in the throat and blood clots such as thrombophlebitis and pulmonary embolism.

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.

PRIMOLUT N (PREE moe loot)

Active ingredient(s): *norethisterone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PRIMOLUT N. **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 PRIMOLUT N.**

Where to find information in this leaflet:

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

1. Why am I taking PRIMOLUT N?

PRIMOLUT N contains the active ingredient norethisterone. PRIMOLUT N is a type of hormone similar to the natural female hormone progesterone. Some of the active ingredient in PRIMOLUT N is converted to estrogen in the body.

PRIMOLUT N is used to treat irregular menstrual periods with heavy and/or persistent bleeding that has no identified cause; lack of menstrual bleeding; premenstrual complaints (premenstrual syndrome); menopausal complaints in combination with estrogen as part of hormone replacement therapy; endometriosis (a disease caused by womb-lining tissue growing outside the womb).

PRIMOLUT N is not to be used as a contraceptive.

2. What should I know before I take PRIMOLUT N?

Warnings

Do not take PRIMOLUT N if:

- you are allergic to norethisterone, 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); the lungs (pulmonary embolism); the heart (heart attack); the brain (stroke); or 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 disabilities, or may even be fatal. You are at an increased risk of having a

blood clot when you take hormonal medicines such as PRIMOLUT N.

- 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 are taking antiviral medicines which contain ombitasvir, paritaprevir, or dasabuvir, and combinations of these. These antiviral medicines are used to treat chronic (long-term) hepatitis C (an infectious disease that affects the liver, caused by the hepatitis C virus).
- you have or have had angina (chest pain)
- you have or have had a mini stroke (also known as a TIA or transient ischaemic attack)
- you have or have had high risk of blood clots due to conditions such as diabetes with blood vessel damage, severe high blood pressure
- you have or have had migraine, where you have also had problems with seeing, speaking or had weakness or numbness in any part of your body
- you have or have had severe liver disease and your liver function values have not returned to normal
- you have or have had a benign or malignant liver tumour
- 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 a condition causing an increase in the breakdown of red blood cells in the body (Dubin-Johnson syndrome or Rotor syndrome)
- you have or have had vaginal bleeding or blood in your urine for which a cause has not been identified
- you have or have had breast disease for which a cause has not been identified
- you have or have had a missed miscarriage.

If any of these conditions appear for the first time while taking PRIMOLUT N, stop taking it at once and tell your doctor.

Check with your doctor if you:

- have diabetes
- have high blood pressure
- have liver disease or a liver tumour
- have a history of depression with hallucinations, delusions
- have epilepsy
- have migraines
- have asthma
- have kidney disease
- have heart disease
- smoke
- 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
- are overweight

- have any hereditary or acquired conditions that may make it more likely for you to get blood clots
- have liver disease
- have jaundice (yellowing of the skin) and/or pruritus (itching of the skin) related to cholestasis (condition in which the flow of bile from the liver stops or slows)
- have gall bladder disease
- have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- have high cholesterol or triglycerides
- have systemic lupus erythematosus (SLE – a disease affecting the skin all over the body)
- have haemolytic uraemic syndrome (HUS – a disorder of blood coagulation causing failure of the kidneys)
- have sickle cell disease
- have a condition that occurred for the first time, or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, a metabolic disease called porphyria, a skin disease called herpes gestationis, a neurological disease called Sydenham's chorea)
- have chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face) – if so, avoid the sun or ultraviolet radiation
- have hereditary angio-oedema, such as swollen face, tongue and/or pharynx and/or difficulty swallowing, or hives together with difficulty in breathing.

If any of the above conditions appear for the first time, recur or worsen while taking PRIMOLUT N, you should talk to 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

Check with your doctor if you are pregnant or intend to become pregnant. Do not take this medicine if you are pregnant or think you might be pregnant. It may affect your developing baby if you take it during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Do not breastfeed if you are taking this medicine. The active ingredient in PRIMOLUT N passes into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to a child.

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.

Do not take this medicine after the expiry date printed on the pack and blister. The expiry date is printed on the carton and on each blister after "EXP" (e.g. 11 18 refers to November 2018). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

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 PRIMOLUT N and affect how it works. These include:

- medicines used to treat epilepsy such as primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate, lamotrigine
- medicines used to treat tuberculosis such as rifampicin
- medicines used to treat fungal infections such as griseofulvin, ketoconazole
- medicines used to treat HIV, such as ritonavir or nevirapine
- some medicines used to treat Hepatitis C Virus (HCV) such as ombitasvir, paritaprevir, or dasabuvir or combinations of these
- etoricoxib, an anti-inflammatory medicine used to treat pain
- tizanidine, melatonin or midazolam which are medicines that relax the body
- theophylline, a medicine that helps with breathing
- medicines used to treat high blood pressure, chest pain and/or irregular heartbeats such as diltiazem, verapamil
- macrolide antibiotics (e.g. clarithromycin, erythromycin)
- herbal medicines containing St John's wort
- cyclosporin, a medicine used to suppress the immune system
- grapefruit juice

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

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

4. How do I take PRIMOLUT N?

How much to take

- PRIMOLUT N is used to treat a number of different conditions. The dosage will vary depending on why you have been given this medicine.
- The recommended dosage can range between 1 tablet daily in some conditions, up to 4 tablets daily in other conditions. Your doctor will advise you on how to take your tablets.
- If you do not understand the instructions printed on the pharmacist label, talk to your doctor or pharmacist.

When to take PRIMOLUT N

- PRIMOLUT N tablets should be swallowed whole with a glass of water. It does not matter if you take it before or after food.

- Depending on your condition you may be prescribed to take PRIMOLUT N for 10 days, or for up to 6 months. Follow the advice of your doctor carefully. Continue taking your medicine for as long as your doctor tells you.
- There are no specific withdrawal symptoms if you stop PRIMOLUT N but there is the possibility that the original complaints might re-occur.

If you forget to take PRIMOLUT N

PRIMOLUT N should be used regularly at the same time each day. If you miss your dose at the usual time, only take the last missed tablet as soon as you remember and then continue taking your tablet at your usual time on the next day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

- The efficacy of PRIMOLUT N could be reduced if you forget to take a tablet as directed.

If you take too much PRIMOLUT N

If you think that you have taken too much PRIMOLUT N, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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 taking PRIMOLUT N?

Things you should do

Call your doctor straight away if you:

- become pregnant while taking this medicine
- feel a lump in your breast
- are immobilised (e.g. due to an accident or you have your leg(s) in a splint/plaster)
- are to have surgery (consult your doctor at least six weeks in advance)
- have unusual, heavy vaginal bleeding
- have been experiencing unusually severe headaches
- develop high blood pressure
- are experiencing abnormal vision
- have severe stomach pain
- are about to be started on any new medicine, remind your doctor and pharmacist that you are taking PRIMOLUT N.

Remind any doctor, dentist or pharmacist, surgeon and anaesthetist (if you are going to have surgery) you visit that you are using PRIMOLUT N.

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.

Keep all of your doctor's appointments so that your progress can be checked.

The risk of having blood clots is temporarily increased as a result of major surgery, any surgery to the legs or pelvis, neurosurgery or major trauma. In women who take PRIMOLUT N, the risk may be higher.

In women at risk of prolonged immobilisation (including major surgery, any surgery to the legs and pelvis, neurosurgery, or major trauma), your doctor may tell you to stop taking (in the case of elective surgery at least 4 weeks in advance) and not resume until two weeks after complete remobilisation. Your doctor may prescribe other treatment (e.g. treatment for blood clots) if PRIMOLUT N has not been discontinued in advance.

Other risk factors for blood clotting include temporary immobilisation including air travel of greater than 4 hours, particularly in women with other risk factors. Consult your doctor if you plan to air travel for greater than 4 hours.

Stop taking PRIMOLUT N and see your doctor immediately if you notice the following signs:

- one-sided swelling of the leg and/or foot or along a vein in the leg
- pain or tenderness in the leg which may be felt only when standing or walking
- increased warmth in the affected leg; red or discoloured skin on the leg
- sudden onset of unexplained shortness of breath or rapid breathing
- sudden coughing or coughing up of blood
- sharp chest pain or sudden severe pain in the chest which may increase with deep breathing
- severe light headedness or dizziness
- rapid or irregular heartbeat
- sudden pain, swelling and slight blue discoloration of an extremity
- sudden numbness or weakness of the face, arm or leg, especially on one side of the body
- sudden trouble walking, dizziness, loss of balance or coordination
- sudden confusion, slurred speech or aphasia; sudden partial or complete loss of vision, double vision, painless blurring of vision which can progress to loss of vision
- sudden, severe or prolonged headache with no known cause
- loss of consciousness or fainting with or without seizure

- pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the chest, arm, or below the breastbone
- discomfort radiating to the back, jaw, throat, arm, stomach
- feeling of being full, having indigestion or choking
- sweating, nausea, vomiting
- extreme weakness and anxiety.

If you have sexual intercourse, you should use non-hormonal methods of contraception (e.g. barrier methods such as condoms or diaphragm). If you think you might have fallen pregnant despite such protective measures, stop taking the tablets and see your doctor immediately.

Things you should not do

- Do not take PRIMOLUT N to treat any other conditions unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or change the dosage without checking with your doctor. If you stop taking it suddenly, your condition may worsen or you may have unwanted effects.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PRIMOLUT N affects you.

Adverse effects of PRIMOLUT N include visual disturbances, dizziness and somnolence, which could affect a person's ability to drive or use machines.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your tablets in the 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.

When to discard your medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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.

Side effects are more common during the first month after starting PRIMOLUT N, and they should subside with duration of treatment.

When used for endometriosis, changes in bleeding pattern including irregular bleeding, scanty bleeding and absence of bleeding may occur.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • nausea • headache, including migraines • fluid retention • shortness of breath • hypersensitivity reactions (e.g. rash, hives) • abnormal vision <p>Progestogen effects:</p> <ul style="list-style-type: none"> • severe allergic like reactions characterised by difficulty breathing, swollen tongue, feeling of tightness in the throat • thrombophlebitis (blood clot in a vein) • pulmonary embolism (blood clot in the lung) • nervousness • difficulty sleeping • drowsiness, tiredness • depression • shaking movements in one or more parts of the body • pre-menstrual type depression • hives, rash, itchiness • acne • hirsutism • hair loss • sweating • irregular uterine bleeding • spotting and lack of period • breast tenderness and discharge • changes in cervical excretions and secretions • high fever • fatty hump between the shoulders, rounded face and pink or purple stretch marks (Cushing's syndrome) • weight gain 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Specific side effects

Blood clots and PRIMOLUT N

Blood clots may block blood vessels in your body. This type of blood clot is also called thrombosis.

Blood clots sometimes occur in the deep veins of the legs (deep venous thrombosis, DVT). 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 (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 PRIMOLUT N.

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

Cancer and PRIMOLUT N

In rare cases benign liver tumours and even more rarely, malignant liver tumours have been reported in users of hormonal substances such as the one contained in PRIMOLUT N. These tumours may lead to internal bleeding.

Contact your doctor immediately if you have severe pain in your abdomen.

Breast cancer has been diagnosed slightly more often in women who take hormonal substances similar to PRIMOLUT N than in women of the same age who do not take these medicines.

It is not known whether the difference is caused by these medicines. 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 lumps.

Cervical cancer has been reported to occur more often in women who have been taking hormonal medicines for a long time. It is not certain if this is caused by hormonal medicines.

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. 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 PRIMOLUT N contains

Active ingredient (main ingredient)	Norethisterone 5 mg
Other ingredients (inactive ingredients)	Lactose monohydrate, maize starch, magnesium stearate
Potential allergens	n/a

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

Tablets do not contain sucrose or gluten. Tablets also do not contain tartrazine or any other azo dyes.

What PRIMOLUT N looks like

PRIMOLUT N comes in a box containing 3 blister strips. Each blister strip contains 10 white tablets marked with "AN" inside a hexagon (AUST R 134491).

Who distributes PRIMOLUT N

Bayer Australia Ltd
ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073

This leaflet was prepared in September 2023.

See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

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