

# PRIMOLUT<sup>®</sup> N (PREE-moe-loot)

norethisterone

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## Consumer Medicine Information

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### WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Primolut N. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Primolut N against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

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### WHAT PRIMOLUT N IS USED FOR

Primolut N is a so-called progestogen, a hormonal product having similarity with the natural female hormone progesterone.

Primolut N is used for timing of menstruation and to treat disturbances of the monthly bleeding (dysfunctional bleeding), lack of the monthly bleeding (primary and secondary amenorrhoea), premenstrual complaints (premenstrual syndrome), in combination with oestrogen hormone replacement therapy, and endometriosis (a disease leading to complaints caused by womb-lining tissue

growing outside the womb, the use of Primolut N leads to shrinking of this unwanted tissue).

**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.

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### BEFORE YOU TAKE PRIMOLUT N

***When you must not take it***

**Do not take Primolut N if you have an allergy to:**

- norethisterone, the active ingredient in Primolut N
- any of the ingredients listed at the end of this leaflet.

**Some of the symptoms of an allergic reaction may include:**

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

**Do not take this medicine if you are pregnant.**

It may affect your developing baby if you take it during pregnancy.

**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 Primolut N:**

- If you have a disorder affecting the blood circulation (thromboembolic processes). In particular those conditions relating to thrombosis (the formation of a blood clot) in the blood vessels of the legs (deep vein thrombosis), the lungs (pulmonary embolism), the heart (heart attack) or the brain (stroke) or other parts of the body.
- If you suffer or have suffered from any disease of the heart or blood vessels.
- If you have diabetes mellitus with blood vessel damage.
- If you suffer or have suffered from a severe liver disease (as long as your liver function values have not returned to normal). Symptoms of a liver disease may be, for instance, yellowing of the skin and/or itching of the whole body.
- If you have or have had a benign or malignant liver tumor.
- If you suffer or have suffered from a malignant sex hormone-dependent tumor such as cancer of the breast or the genital organs.
- If you suffer from a condition called Dubin-Johnson syndrome or Rotor syndrome.
- If you have vaginal bleeding or blood in your urine for which a cause has not been identified.
- If you have breast disease for which a cause has not been identified.
- If you have had a miscarriage.

If any of these conditions appear for the first time while using Primolut

N, stop taking it at once and consult your doctor.

**Do not take this medicine if the packaging is torn or shows signs of tampering or the tablets don't look right.**

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 09 refers to November 2009). 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.**

***Before you start to take it***

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if:**

- you smoke
- you are overweight
- you or anyone in your immediate family has had blood clots in the legs (thrombosis), a heart attack, a stroke, breast cancer or high cholesterol.

**Tell your doctor if you have or have had any of the following medical conditions:**

- you have diabetes
- you have high blood pressure
- you have liver disease or a liver tumor
- 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

- you have a history of psychic depression
- you have epilepsy
- you suffer from migraine
- you have asthma
- you have kidney disease
- you have heart disease.

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

### ***Primolut N and thrombosis***

Thrombosis is the formation of a blood clot that 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. It has been concluded from epidemiological surveys that the use of oral oestrogen/progestogen containing ovulation inhibitors is attended by an increased incidence of thromboembolic diseases.

Therefore, one should keep the possibility of an increased thromboembolic risk in mind, particularly where there is a history of thromboembolic diseases. It is generally recognised that the risk for venous thromboembolism increases for example with increasing age, if you are overweight, if you have had venous thromboembolism or if anyone in your immediate family has had a thrombosis (venous thromboembolism in a sibling or a parent at a relatively early age). 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 take Primolut N the risk may be yet higher. Tell your doctor you are taking Primolut N well in advance of any expected hospitalisation or surgery. Your doctor may tell you to stop taking Primolut N several weeks before surgery or at the time of immobilisation. Your doctor will also tell you when you can start taking Primolut N again after you are back on your feet.

The risk of thromboembolism is also increased shortly after childbirth.

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

If you develop high blood pressure while taking Primolut N, you may be told to stop taking it.

Very occasionally thrombosis may cause serious permanent disabilities or may even be fatal.

If you notice possible signs of a thrombosis, stop taking Primolut N and consult your doctor immediately.

### ***Primolut N and cancer***

In rare cases benign liver tumors and even more rarely, malignant liver tumors have been reported in users of hormonal substances such as the one contained in Primolut N. These tumors may lead to internal bleeding. Contact your doctor immediately if you have severe pain in your abdomen.

### ***Primolut N and ability to drive***

There are no known effects.

### ***What happens once you stop taking Primolut N***

There are no specific withdrawal symptoms if you stop Primolut N but there is the possibility that the original complaints might re-occur.

### **Taking other medicines**

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

Some medicines and Primolut N may interfere with each other.

These include:

- medicines that increase the metabolism of Primolut N, e.g. some of those used for the treatment of epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine)
- medicines used to treat tuberculosis (e.g. rifampicin, rifabutin)
- antifungals (e.g. griseofulvin)
- herbal medicines containing St John's Wort.

**Your doctor and pharmacist have more information on medicines that you need to be careful with or avoid while taking this medicine.**

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## **HOW TO TAKE PRIMOLUT N**

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions printed on the pharmacist label, ask your doctor or pharmacist for help.**

### **How to take it**

**Swallow the tablets whole with a glass of water.**

If you have sexual intercourse, you should use non-hormonal methods (e.g. barrier methods) of contraception. If you think you might have fallen pregnant despite such protective measures, stop taking the tablets and see your doctor. He/she will check you are not pregnant before you can recommence tablet taking. Your doctor will advise you on how to take your tablets. The dosage will vary depending on why you have been given this medicine. The following dosages are recommended:

### **Dysfunctional bleeding (Disturbances of your period)**

Take 1 tablet 3 times daily for 10 days. In most cases bleeding will stop within 1 to 3 days, but Primolut N must be taken for the full 10 days. About 2 to 4 days after you stop taking the tablets, withdrawal bleeding will occur with the intensity and duration of normal menstruation.

Occasionally, slight bleeding may reoccur after the initial bleeding stops. If this happens do not stop taking the tablets. Keep taking the tablets for the full 10 days.

If vaginal bleeding does not stop, despite taking the tablets correctly or if, after an initial suspension of bleeding, fairly heavy bleeding reoccurs while you are taking the tablets, you should contact your doctor. Your doctor will need to consider other causes for the bleeding. To prevent dysfunctional bleeding from re-occurring your doctor may decide that you should take Primolut N regularly (1 tablet 1 to 2 times daily from the 16th to the 25th day of the cycle (1st day of the cycle = 1st day of the last bleeding). Withdrawal bleeding occurs a few days after the last tablet intake. If

you are unsure about when to take the tablets ask your pharmacist or doctor.

### **Primary and secondary amenorrhoea (lack of a period)**

Hormone treatment of secondary amenorrhoea can be carried out only after the exclusion of pregnancy. Primary or secondary amenorrhoea is sometimes caused by a prolactinoma (an alteration of a gland in the brain producing increased amounts of a hormone-like substance) which needs to be excluded by your doctor before starting treatment with Primolut N. Your doctor will prescribe you an oestrogen (usually for 14 days) before you begin treatment with Primolut N. You then take 1 tablet of Primolut N 1 to 2 times daily for 10 days. Withdrawal bleeding occurs a few days after taking the last tablet.

If sufficient oestrogen production by your body has been achieved, your doctor may try to stop the oestrogen treatment and to induce cyclical bleeding by just administering 1 tablet of Primolut N twice daily from the 16th to the 25th day of the cycle. If you are unsure about when to take the tablets ask your doctor or pharmacist.

### **Premenstrual syndrome**

Take one tablet 1 to 3 times daily during the 2<sup>nd</sup> half (luteal phase) of the cycle may relieve or improve premenstrual symptoms such as headaches, depressive moods, water retention, and a feeling of tension in the breasts.

### **Timing of menstruation**

Monthly menstrual bleeding can be delayed by taking Primolut N. However, this method should be used by you only if you are not at risk of pregnancy during the treatment cycle.

Dosage: Take 1 tablet 2 to 3 times daily for no longer than 10 to 14 days, beginning about 3 days before expected menstruation. Bleeding will occur 2 to 3 days after you stop taking the tablets.

### **Endometriosis**

Treatment should begin between the first and 5th day of the cycle with 1 tablet twice daily. In the event of spotting, the dose can be increased to 2 tablets twice daily. If bleeding stops, dose reduction to the initial dose should be considered.

Treatment is to be continued for at least 4 to 6 months. With uninterrupted daily intake, ovulation and menstruation do not usually occur. After discontinuation of hormone treatment withdrawal bleeding will occur.

### ***If you forget to take it***

The efficacy of Primolut N could be reduced if you forget to take a tablet as directed. You should only take the last missed tablet, as soon as you remember, and then continue tablet intake at your usual time on the next day.

Do not take a double dose to make up for forgotten individual doses.

### ***If you take too much (overdose)***

**Immediately telephone your doctor or the Poisons Information Centre (Australia: 13 11 26 or New Zealand: 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Primolut N.**

**Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

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## **WHILE YOU ARE TAKING PRIMOLUT N**

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### ***Things you must do***

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Primolut N.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.** It may affect other medicines used during surgery.

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

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

- you notice any changes in your health, especially involving any of the items mentioned in this leaflet (see also: "Before you take Primolut N"; 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 (see "Before you take Primolut N")
- you are to be immobilised or are to have surgery (consult your doctor at least six weeks in advance)
- you have unusual, heavy vaginal bleeding
- you have been experiencing unusually severe headaches;

- you are experiencing abnormal vision
- you have severe stomach pain.

**Stop taking tablets and see your doctor immediately if you notice possible signs of thrombosis:**

- 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.

**The situations and symptoms mentioned above are described and explained in more detail elsewhere in this leaflet.**

### ***Things you must not do***

**Do not take Primolut N to treat any other complaints 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 lower the dosage without checking with your doctor.**

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

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## **SIDE EFFECTS**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Primolut N.**

This medicine helps most people, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

Side effects are more common during the first months after the start of intake of Primolut N, and subside with duration of treatment. In addition to the adverse effects listed in the section entitled “**Before you take Primolut N**” the following side effects have been reported in users of Primolut N, although these effects may not necessarily be caused by Primolut N:

In the indication of endometriosis, changes in bleeding pattern including irregular bleeding, scanty bleeding and the absence of bleeding may occur.

Other side effects that have been reported in users of Primolut N are:

- abnormal vision
- nausea
- headache
- fluid retention
- migraine
- shortness of breath and
- hypersensitivity reactions (e.g rash, hives).

The following events although not reported for Primolut N, have been associated with the use of other progestogens:

- anaphylaxis and anaphylactoid-like reactions

- thrombophlebitis
- pulmonary embolism
- nervousness
- problems with sleeping
- drowsiness
- tiredness
- depression
- dizziness
- tremor
- pre-menstrual type depression
- hives
- itchiness
- rash
- acne
- hirsutism
- hair loss
- sweating
- irregular uterine bleeding
- spotting and lack of menstruation
- breast tenderness and discharge
- changes in cervical excretions and secretions
- high fever
- Cushing’s syndrome
- weight gain
- moderate elevation of blood pressure
- transient elevation of certain liver enzymes
- elevations of serum calcium and potassium levels
- increases in white cell and platelet counts.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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## **AFTER TAKING PRIMOLUT N**

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### **Storage**

**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.**

**Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.**

**Do not leave it in the car.** Heat and damp can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### **Disposal**

**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.**

**Return any unused medicine to your pharmacist.**

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## **PRODUCT DESCRIPTION**

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### **What it looks like**

Primolut N comes in a box containing 3 blister packs. Each blister pack contains 10 white tablets marked with “AN” inside a hexagon.

### **Ingredients**

Active ingredients per tablet:

- Primolut N – 5 mg norethisterone

Inactive ingredients:

- lactose
- maize starch
- magnesium stearate

### **Supplier**

Made in Germany for:

Bayer Australia Limited

ABN 22 000 138 714  
875 Pacific Highway  
Pymble NSW 2073

Bayer New Zealand Limited  
3 Argus Place, Hillcrest,  
North Shore  
Auckland 0627

***Australian registration  
number***

Primolut N (blisters) – AUST R  
134491

***Date of Preparation***

October 2011

See TGA website ([www.tga.gov.au](http://www.tga.gov.au))  
for latest Australian Consumer  
Medicine Information.

See MEDSAFE website  
([www.medsafe.govt.nz](http://www.medsafe.govt.nz)) for latest  
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