

PRIMOLUT® N

(PREE·moe·loot)

Norethisterone

Consumer Medicine Information

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 for more advice.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT PRIMOLUT N IS USED FOR

Primolut N contains a hormone, norethisterone. This type of hormone is similar to the natural female hormone progesterone. Some of the information in this leaflet is based on experience with estrogen containing oral contraceptives as some of the active ingredient in Primolut N is converted to estrogen in the body.

However, Primolut N is not to be used as a contraceptive 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)

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.

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 or think you might be 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 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)
- other parts of the body

Do not take Primolut N if 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.

Do not take Primolut N if 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.

Do not take Primolut N if 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).

Do not take Primolut N if you have or have had:

- angina (chest pain)
- mini stroke (also known as a TIA or transient ischaemic attack)
- high risk of blood clots due to conditions such as diabetes with blood vessel damage, severe high blood pressure
- migraine, where you have also had problems with seeing, speaking or had weakness or numbness in any part of your body
- severe liver disease and your liver function values have not returned to normal
- a benign or malignant liver tumour.
- cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs)
- a condition causing an increase in the breakdown of red blood cells in the body (Dubin-Johnson syndrome or Rotor syndrome)
- vaginal bleeding or blood in your urine for which a cause has not been identified
- breast disease for which a cause has not been identified.
- 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.

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.

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 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.

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

- diabetes
- high blood pressure
- liver disease or a liver tumour you have a history of depression with hallucinations, delusions
- epilepsy
- migraine
- asthma
- kidney disease
- heart disease.

Ask your doctor to check if you:

- 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 – you should see your doctor immediately if you experience symptoms of 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 tell your doctor.

If you have not told your doctor about any of the above, tell him/her before you start taking Primolut N.

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 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 medicines, or prescribe a different medicine.

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

HOW TO TAKE PRIMOLUT N

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 on the pack ask your doctor or pharmacist for help.

How to take it

Swallow each tablet whole with a glass of water.

It does not matter if you take it before or after food.

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.

How long to take it

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.**

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 taking your tablet 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) 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.

WHILE YOU ARE TAKING PRIMOLUT N

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.

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 or pelvis, neurosurgery, or major trauma), your doctor may tell you to stop taking (in the case of elective surgery at least four 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 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.

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.

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

Contact your doctor as soon as possible if you:

- 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.

Things you must 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 side effects.

SIDE EFFECTS

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 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 the absence of bleeding may occur.

Tell your doctor if you notice any of the following and they worry you:

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

The following events have been associated with the use of progestogens:

- severe allergy 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
- dizziness
- 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

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.

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 possible 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.

AFTER TAKING PRIMOLUT N

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.

PRODUCT DESCRIPTION

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:

- 5 mg of norethisterone

Inactive ingredients:

- lactose monohydrate
- maize starch
- magnesium stearate

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

Supplier

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

*Australian registration
number*

Primolut N (blisters) – AUST R
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June 2018

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

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