



Package leaflet – information for the user

Primolut N 5 mg Tablets

Norethisterone

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again.

If you have more questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Primolut N is and what it is used for
2. Before you take Primolut N
3. How you take Primolut N
4. Possible side effects
5. How to store Primolut N
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1. What Primolut N is and what it is used for

Primolut N contains norethisterone, which belongs to a group of medicines called *progestogens*, which are female hormones.

Primolut N can be used:

- to treat irregular, painful or heavy periods
- to treat endometriosis (where tissue from the lining of the womb is present in places where it is not normally found)

2. Before you take Primolut N

Before you can begin taking Primolut N, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure, and

depending upon your personal situation, may also carry out some other tests.

Do not take Primolut N if you are:

- **allergic** to norethisterone or any of the other ingredients. The ingredients are listed in section 6
- **pregnant** or if you think you might be pregnant
- **breastfeeding**

or if you have:

- any **unexplained bleeding from the vagina**
- (or are recovering from) a **liver disease** and the blood tests show that your liver is not yet working normally.
- (or have ever had) **liver cancer**.

Do not take Primolut N if you have:

- (or ever have had) **blood clots** in the legs or lungs, a heart attack or stroke (see also "Other things you should know")
- (or ever have had) any medical condition which can be an early sign of a future heart attack (such as angina which causes severe chest pain which may spread to the left arm) or stroke (such as a minor stroke with no lasting effects, a so-called transient ischemic attack (TIA))
- a high risk of getting blood clots
- (or ever had) migraine headaches with related visual symptoms, speech problems or weakness or numbness in any part of your body
- **diabetes mellitus** with changes to the blood vessels
- **breast cancer** or cancer of the genital organs.

Do not use Primolut N if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir (see also in section Other medicines and Primolut N)

To reduce the risk of blood clots, treatment with Primolut N must be stopped:

- six weeks before any planned major operation
- before any surgery to the legs
- before medical treatment for varicose veins
- if you are going to be immobilised for a long time (e.g. if you need bed-rest after an accident or operation, or if you have a plaster cast on a broken leg).

Tell your doctor if any of these apply to you and **do not take Primolut N**.

If any of these conditions develops or worsens while you are using Primolut N, talk to your doctor. Primolut N must be stopped.

Take special care with Primolut N:

The sexual steroid (progesterone) that this product contains is partly converted into estrogen. Therefore, the general warnings associated with the use of combined oral contraceptives (the "pill") should also be considered for Primolut N.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Primolut N.

In some situations, you need to take special care while on Primolut N and your doctor may need to examine you regularly. Consult your doctor before starting to use Primolut N, if any of the following conditions apply to you or if any of them develop or worsen while you are taking Primolut N.

- if you **smoke**
- if you have **diabetes** (metabolic disease with elevated sugar levels). Primolut N can produce changes in blood sugar level.
- You are **seriously overweight**
- if you have **high blood pressure**
- if you have a heart valve disorder or heart rhythm disorder
- if you or someone in your family have had **blood clots**, a heart attack or a stroke at a young age
- if you have varicose veins
- if your veins are inflamed (*superficial phlebitis*)



- if you or anyone in your immediate family has had **breast cancer**
- you have or have had a condition with yellowish-brown patches on your skin especially your face (chloasma). If you have had chloasma, avoid too much exposure to the sun or ultraviolet rays
- you have or have had **depression**
- if you suffer from migraine
- if you suffer from epilepsy (see Other Medicines and Primolut N)
- if you or someone in your family has or has had high blood cholesterol or triglyceride (fat) levels
- If you have a disease of the liver or gall bladder
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- if you have systemic lupus erythematosus (or SLE, a disease of the immune system)
- if you have hemolytic uremic syndrome (or 'HUS', a disorder of blood coagulation causing failure of the kidneys)
- if you have sickle cell disease
- if you 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, or a neurological disease called Sydenham's chorea)
- if you have hereditary angioedema. Consult your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue or throat, and/or difficulty swallowing, or hives, together with difficulty breathing. Products containing estrogens may induce or worsen symptoms of angioedema
- you have an **intolerance to some types of sugar (galactose intolerance, Lapp**

lactase deficiency or glucose-galactose malabsorption).

- if you have elevated levels of fat in the blood (hypertriglyceridemia) or a positive family history for this condition. Hypertriglyceridemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas).

Tell your doctor before you take Primolut N if any of these applies to you. Also tell your doctor if you are giving a blood sample. Primolut N may interfere with the results of certain blood tests.

Other things you should know:

Once you have finished taking a course of Primolut N, you will usually have a menstrual bleed (period) 2-3 days after taking your last tablet. If you do not have a period, you must make sure that you are not pregnant before taking any more tablets.

Primolut N and blood clots

The risk of blood clots occurring in veins and arteries is greater in women who take the combined oral contraceptive pill than in women who don't. The blood clot may block a deep vein in the legs (*deep vein thrombosis*). This blood clot can sometimes move from the veins in the leg to another part of the body (e.g. lungs) at which point it is known as an embolus. Venous thromboembolism (VTE) is a term used to describe both types of blood clot. VTE may occur whether you are taking the Pill or not. It can also happen in pregnancy. People do not always fully recover from such blood clots, which can cause heart attacks, strokes and bleeding into the brain (*subarachnoid haemorrhage*). In extremely rare cases, blood clots can occur in other parts of the body including the liver, gut, kidney, brain or eye. Although Primolut N is not an oral contraceptive, the risk of developing blood clots still exists. The risk is two to threefold higher than for non-pill users who are not pregnant and remains lower than the risk associated with pregnancy and delivery of the baby.

The risk may also be higher if you have recently had a baby.

The risk is highest during the first year of use, especially in the first three months after starting the pill for the first time or re-starting the pill after a break of 4 weeks or longer.

The risk of venous or arterial blood clots (e.g. deep venous thrombosis, pulmonary embolism, heart attack) or stroke increases:

- with age
- if you are overweight
- if anyone in your immediate family has ever had a blood clot in the leg, lung or elsewhere, a heart attack or a stroke at a young age, or if you or any of your relatives are known or suspected of having a hereditary blood clotting disorder increasing your risk for developing blood clots. In this case you should see a specialist before deciding about using any combined oral contraceptive. Certain blood factors that may suggest you have a tendency for venous or arterial thrombosis include activated protein C (APC) resistance, hyperhomocysteinemia, antithrombin-III deficiency, protein C deficiency, protein S deficiency, antiphospholipid antibodies (anticardiolipin antibodies, lupus anticoagulant)
- with prolonged immobilisation (for example, when you have your leg or legs in plaster or splints), major surgery, any surgery to the legs or major trauma. In these situations, it is better to stop taking the pill (if the surgery is planned you should stop at least four weeks beforehand) and not to start again until two weeks after you are fully on your feet again
- if you smoke (the risk increases the more you smoke and the older you get, especially in women over 35 years of age). When using the pill, you should stop smoking, especially if you are older than about 35 years of age
- if you or someone in your immediate family has or has ever had high blood levels of cholesterol or triglycerides (fatty substances)
- if you have high blood pressure. If you develop high blood pressure while using the pill, you may be told to stop using it
- if you suffer from migraine
- if you have a heart valve disorder or a certain heart rhythm disorder



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** (see 4. Possible side effects, Reasons for stopping Primolut N immediately).

Primolut N and cancer

Breast cancer has been seen slightly more often in women using combined pills, but it is not known whether this is caused by the treatment itself. For example, it may be that more tumors are detected in women on combined pills because they are examined by their doctor more often.

The risk of breast tumors becomes gradually less after stopping the combined hormonal contraceptive. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

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. The most important risk factor for cervical cancer is persistent Human Papilloma Virus (HPV) infection. Some studies suggest that long-term use of the pill increases a woman's risk of developing cervical cancer. However, it is not clear to what extent sexual behavior or other factors, such as HPV, increase this risk. The tumors mentioned above may be life-threatening or may have a fatal outcome.

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

Other medicines and Primolut N

Please tell your doctor if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription.

Some medicines may stop Primolut N from working properly. Also Primolut N may change the way other medicines you are taking are broken down in your body.

Some medicines

- can have an influence on the blood levels of Primolut N
- can make it less effective
- can cause unexpected bleeding

- These include medicines used for the treatment of:
 - epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbamazepine, topiramate, felbamate)
 - tuberculosis (e.g. rifampicin)
 - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors, e.g. ritonavir, nevirapine, efavirenz)
 - fungal infections (griseofulvin, azole antifungals, e.g. itraconazole, voriconazole, fluconazole)
 - bacterial infections (macrolide antibiotics, e.g. clarithromycin, erythromycin)
 - certain heart diseases, high blood pressure (calcium channel blockers, e.g. verapamil, diltiazem)
 - arthritis, arthrosis (etoricoxib)
 - high blood pressure in the blood vessels in the lung (bosentan)
 - products containing the herbal remedy St. John's Wort (*Hypericum perforatum*)
 - grapefruit juice
- Primolut N may influence the effect of other medicines e.g.:
- medicines containing cyclosporine
 - the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures)
 - theophylline (used to treat breathing problems)
 - tizanidine (used to treat muscle pain and/or muscle cramps)

Do not use Primolut N if you have Hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir as this may cause increases in liver function blood test results (increase in ALT liver enzyme). Primolut N can be restarted approximately 2 weeks after completion of this treatment. See section "Do not use Primolut N".

While you are using Primolut N, your doctor will tell you to return for regular check-ups.

Pregnancy and breastfeeding

Do not take Primolut N if you are pregnant. If you think you might be

pregnant or are planning a family, tell your doctor before taking Primolut N. Do not take Primolut N if you are breastfeeding.

Driving and using machines

Primolut N is unlikely to affect your ability to drive or use machines.

3. How you take Primolut N

Swallow the tablets whole with a drink of water.

The effectiveness of Primolut N could be reduced if the user forgets to take a tablet as directed.

To treat irregular, painful or heavy periods

One tablet taken three times a day for 10 days. Bleeding should stop within a few days (1-3 days). Sometimes slight bleeding/spotting may occur. Do not stop taking your tablets if this happens. If the bleeding does not stop, even when the tablets are taken correctly, talk to your doctor.

To prevent recurrence of irregular, painful or heavy periods

One tablet taken one to two times a day from day 16 to day 25 of the cycle.

Endometriosis

One tablet taken twice a day starting between the first and the 5th day of the cycle and continuing for 4 to 6 months. Your doctor may increase the dose to two tablets twice a day if spotting occurs.

Once you stop taking the tablets, withdrawal bleeding (like a period) will occur.

If you have sexual intercourse, you should use non-hormonal barrier methods of contraception (for example, a condom) instead of taking a contraceptive pill. Tell your doctor if you think you might have become pregnant and do not take Primolut N.

If you take too many tablets

Taking too many tablets is unlikely to cause serious problems. If you take too many, contact your doctor who will tell you what to do.

If you forget to take the tablets

Primolut N may have less effect if you miss a dose. If you forget a dose, wait until it is time to take the next prescribed dose. Do not take the missed dose. If you are worried, contact your doctor or pharmacist.

4. Possible side effects



Reasons for stopping Primolut N immediately:

Stop taking Primolut N and speak to your doctor immediately if you experience any of the following:

- migraine for the first time
- unusually bad headaches, occurring more often than before
- sudden changes to your eyesight, hearing or speech
- sudden changes to your sense of smell, taste or touch
- symptoms of blood clot formation or symptoms of inflammation of the veins combined with the formation of blood clots (*thrombophlebitis*):
 - unusual pains in your leg(s)
 - unusual swelling of your arms or legs
 - sharp pains in your chest or sudden shortness of breath
 - crushing pains or feelings of heaviness or tightness in your chest
 - coughing for no apparent reason
 - one side of your body suddenly becoming very weak or numb
 - dizziness or fainting.

Primolut N must also be stopped immediately if:

- you become pregnant
- you develop jaundice or other liver problems
- you develop itching (*pruritus*), rash or other signs of an allergic reaction such as difficulty breathing or swallowing, swelling of the face, eyes or tongue
- your doctor finds that your blood pressure is too high.

General side effects:

Side effects are more common at the start of treatment. As well as the side effects mentioned under 'Reasons for stopping Primolut N immediately', other side effects that have been reported include:

- changes in bleeding pattern including spotting, weak periods (*hypomenorrhoea*) or no periods (*amenorrhoea*) in patients taking Primolut N for endometriosis
- headache
- feeling slightly sick (*nausea*)
- migraine
- skin problems

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971 Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Primolut N

Keep this medicine out of the reach and sight of children.

Store below 25°C.

Do not use after the expiry date which is marked on both the outer container and on each blister strip of tablets. The expiry date refers to the last day of that month.

Do not dispose of medicines in waste water or household rubbish. Any unused Primolut N should be returned to a pharmacist (chemist) who will dispose of them properly. This helps the environment.

6. Further information

What Primolut N contains

Each tablet contains 5 mg of the active ingredient, norethisterone. The other ingredients are lactose monohydrate, maize starch and magnesium stearate (E572).

What's in the pack

Each pack contains 30 tablets.

Each white tablet has 'AN' embossed in a regular hexagon on one side.

Marketing authorisation Holder

Bayer Limited
The Atrium
Blackthorn Road
Dublin 18

Manufacturer

Bayer AG
13342 Berlin, Germany

or

Bayer Weimar GmbH und Co KG
Dobereinerstraße 20, 99427 Weimar
Germany

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