This area must be identical on both sides!

Package leaflet: Information for the user

Primolut® N

5 mg tablets
(norethisterone)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

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

If you have any further questions, ask your doctor or pharmacist.

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

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. **What Primolut N is and what it is used for**
2. **What you need to know before you take Primolut N**
3. **How to take Primolut N**
4. **Possible side effects**
5. **How to store Primolut N**
6. **Contents of the pack and other information**

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 in several different circumstances:

- 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)
- to treat premenstrual syndrome (also known as premenstrual tension, PMS or PMT)
- to delay periods

2. What you need to know before you take Primolut N

- Your doctor will discuss your medical and family history with you. Your doctor will also need to check your blood pressure and make sure you are not pregnant. You may also need additional checks, such as a breast examination, that will be specific to your medical needs and/or concerns.

Do not take Primolut N:

- **if you are allergic** to norethisterone or any of the other ingredients of this medicine (listed in section 6)
- **if you are pregnant** or if you think you might be pregnant
- **if you are breast-feeding**

or:

- **if you have** ever had a problem with your blood circulation. This includes a **blood clot** (*thrombosis*) in the legs (*deep vein thrombosis*), lungs (*pulmonary embolism*), heart (**heart attack**), brain (**stroke**) or any other parts of the body
- **if you have** any **symptoms of a blood clot**, such as **chest pain, unexplained** and often **sudden shortness of breath** and/or **cough**
- **if you have** any condition which makes you **more at risk of a blood clot** (*thrombosis*)
- **if you have** ever suffered **migraine** with visual disturbance
- **if you have** (or are recovering from) a **liver disease** and the blood tests show that your liver is not yet working normally
- **if you have** (or have ever had) **liver tumours**
- **if you have diabetes** with damaged blood vessels
- **if you have any type of cancer which might be made worse by exposure to female sex hormones** (including breast cancer)
- **if you have** problems with **genital bleeding** for which the cause is not yet known
- **if you have** a condition called **endometrial hyperplasia** which has not been treated.

In addition, do not take Primolut N if you have had any of the following conditions when you were pregnant:

- yellowing of the skin (**idiopathic jaundice of pregnancy**)
- itching of the whole body (**pruritus of pregnancy**)

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Primolut N

- if you smoke
- if you have **diabetes.** Primolut N can produce changes in blood sugar levels. If you are diabetic, your doctor will check your blood sugar before starting treatment and regularly during treatment
- if you are overweight (**BMI ≥ 30 kg/m²**)
- if you have **high blood pressure**
- if you have a **heart valve disorder** or a certain **heart rhythm disorder** (heart problems)
- if you have had a **thrombosis/embolism** or anyone in your close family has had a thrombosis, a heart attack or a stroke at a young age
- if you suffer from **migraine, asthma,** or **kidney problems**
- if you suffer from **epilepsy** (see "Other medicines and Primolut N")
- if you have an **inflammation of your veins** (superficial phlebitis)
- if you have **varicose veins**
- if anyone in your immediate family has had **breast cancer**
- if you have previously had a condition called **chloasma** where the skin on your face may develop brownish blotches. You may be advised to avoid exposure to the sun and to ultraviolet light while you are taking Primolut N
- if you have previously suffered from **depression**
- if you or someone in your close family has ever had **high blood levels of cholesterol** or **triglycerides** (fatty substances)
- if you have a disease of the liver or gall bladder
- if you have certain rare medical conditions such as **systemic lupus erythematosus** (SLE), **sickle cell disease, Crohn's disease** or **ulcerative colitis**
- if you have **haemolytic uremic syndrome** (HUS)
- 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**, **porphyria**, or **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 oestrogens may induce or worsen symptoms of angioedema
- if you have an **intolerance to some types of sugar (galactose intolerance, Lapp lactase deficiency** or **glucose-galactose malabsorption)**
- if you are using other medications as mentioned in "Other Medicines and Primolut N".

→ **Tell your doctor** before you take Primolut N if any of these applies to you. Also tell your doctor if any of these conditions develop or worsen while you are taking Primolut N, because you may need to stop taking it.

Primolut N and blood clots:

The main ingredient in Primolut N (progestogen) is partly converted into oestrogen so you should also consider the general warnings given for combined oral contraceptive pills ("the Pill").

Do not take Primolut N if you have a **blood clot** or have any medical condition which makes you more at risk of developing clots.

The risk of blood clots occurring in the veins and arteries is slightly greater in women who take the combined oral contraceptive pill than in women who don't. People do not always fully recover from such blood clots, which can cause strokes, heart attacks and bleeding into the brain (*subarachnoid haemorrhage*). In very rare cases these blood clots can be fatal.

You are more at risk of having a blood clot:

- as you get **older**
- if you're **off your feet for a long time** because of major surgery, injury or illness.
- if you **smoke**
- if you or any of your close family have had **blood clots**
- if you are overweight (**BMI ≥ 30 kg/m²**)
- if you have a **disorder of blood fat** (lipid) **metabolism**
- if you have a **blood disorder**
- if you have **high blood pressure**
- if you suffer from **migraines**
- if you have a **heart valve disorder** or a particular type of **irregular heartbeat** (atrial fibrillation)
- if you have **recently had a baby**
- if you have **diabetes**
- if you have certain medical conditions such as **systemic lupus erythematosus** (SLE), **sickle cell disease, Crohn's disease** or **ulcerative colitis**

→ **Tell your doctor if any of these apply to you.** Taking Primolut N may add to this risk so it may not be suitable for you.

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)

Signs of a blood clot include:

- a **migraine** for the first time or one that is worse than normal
- unusually frequent or severe **headaches**
- any sudden **changes to your eyesight** (such as loss of vision or blurred vision)
- any sudden **changes to your hearing, speech, sense of smell, taste or touch**
- **pain or swelling in your leg**
- **stabbing pain when you breathe**
- **coughing** for no apparent reason
- **breathlessness**
- **pain and tightness in the chest**
- sudden **weakness** or **numbness** in one side or part of your body
- **dizziness** or **fainting.**

→ **See a doctor as soon as possible if you notice any possible signs of blood clot.** Do not take any more Primolut N until your doctor says you can.

Primolut N and cancer

If you have **breast cancer,** or have had it in the past, you should not take combined oral contraceptives (the Pill). The Pill slightly increases your risk of breast cancer. This risk goes up the longer you're on it, but returns to normal within about 10 years of stopping it. Because breast cancer is rare in women under the age of 40, the extra cases of breast cancer in current and recent Pill users is small. For example:

- Of 10,000 women who have **never taken the Pill**, about **16** will have breast cancer by the time they are 35 years old.

→ **Please turn over**

Packaging Technology Berlin GmbH page 1 Bayer AG
client: L386 material no.: 85996428 PZ: 25981-4 code no.: 36
name: LF-Primolut N 5MG TAB 68 quality: GBL/BAG
colors: BLACK version: 01.00 17.2017/01 Restricted Document dimension: 420 x 160 mm
Digital unterschrieben von Peter Wittmuetz
DN: cn=Peter Wittmuetz, c=DE, o=Bayer, ou=Bayer, email=peter.wittmuetz@bayer.com, cn=Peter Wittmuetz
Datum: 2017.07.26 07:46:30 +02'00'
Peter Wittmuetz
85996428_01.indd 1 7/21/2017 11:23:06 AM

7/21/2017 11:23:36 AM

This area must be identical on both sides!

85996428_01.indd 2

- Of 10,000 women who **take the Pill for 5 years in their early twenties**, about **17–18** will have breast cancer by the time they are 35 years old.
- Of 10,000 women who have **never taken the Pill**, about **100** will have breast cancer by the time they are 45 years old.
- Of 10,000 women who **take the Pill for 5 years in their early thirties**, about **110** will have breast cancer by the time they are 45 years old.

Your risk of breast cancer is higher if:

- you have a close relative (mother, sister or grandmother) who has had breast cancer
- you are overweight (**BMI ≥ 30 kg/m²**)
- → **See a doctor as soon as possible if you notice any changes in your breasts,** such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.

Very rarely, the Pill has been linked with some forms of liver cancer in women who take it for a long time. These may lead to bleeding in the abdomen.

Taking the Pill has also been linked to liver diseases, such as jaundice and non-cancerous liver tumours, but this is rare.

→ **See a doctor as soon as possible if you get severe pain in your stomach that does not go away, or yellow skin or eyes (jaundice).** You may need to stop taking Primolut N.

Other medicines and Primolut N

→ **Tell your doctor** if you are taking, have recently taken or might take any other medicines.

Some medicines may affect the way Primolut N works. **Tell your doctor** if you are taking:

- **Phenytoin, oxcarbazepine, primidone** or **carbamazepine**. These drugs are often used to treat epilepsy.
- Sedative drugs called **barbiturates**.
- The antibiotic drugs **rifampicin** or **rifabutin**.
- An antifungal drug called **griseofulvin**.
- **St John's wort** to treat depression.

Some other medicines may be affected by Primolut N. Tell your doctor if you are taking a drug called ciclosporin which is often used after an organ transplant.

Taking Primolut N can affect the results of some blood and urine tests. Tell your doctor that you are taking Primolut N if you are asked to provide a blood or urine sample.

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.

Pregnancy and breast-feeding

Do not take Primolut N if you are pregnant or **breast-feeding.** If you think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

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

Primolut N contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Primolut N

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The number of tablets that you need to take and the number of days per month when you need to take them will depend on why the doctor has prescribed Primolut N. A common dosage would be 2-3 tablets each day. For some conditions Primolut N has to be taken every day, but this is not always the case.

Ask your doctor or pharmacist, if you are not sure about the number of tablets that you need to take, when they should be taken or how long you should take them for.

Swallow the tablets whole with a drink of water.

If you take more Primolut N than you should

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 Primolut N

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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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 senses 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

Primolut N must also be stopped immediately if:

- you become pregnant
- you develop jaundice or other liver problems
- you develop itching (pruritus)
- your doctor finds that your blood pressure is too high

General side effects:

Side effects that have been reported with Primolut N are listed below according to the frequency with which they occur.

Very common side effects

(These may affect more than 1 in 10 people)

- Vaginal bleeding, including spotting.
- Periods that are much shorter than normal and where blood flow is reduced.

Common side effects

(These may affect up to 1 in 10 people)

- Headache
- Feeling sick (nausea)
- Absence of a period
- Swelling

Uncommon side effects

(These may affect up to 1 in 100 people)

- Migraine

Rare side effects

(These may affect up to 1 in 1,000 people)

- Allergic reactions including skin rash or "hives"

Very rare side effects

(These may affect up to 1 in 10,000 people)

- Visual disturbances
- Difficulty in breathing

Other side effects

(Frequency not known: frequency cannot be estimated from the available data)

- Worsening of depression
- Dizziness
- Abdominal pain
- Jaundice
- Cholestasis

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

Malta

ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Primolut N

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

Store in the original carton.

Do not use this medicine after the expiry date which is stated on both the outer carton and on each blister strip of tablets after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Primolut N contains

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

What Primolut N looks like and contents of the pack

Each pack contains 30 tablets (3 foil blister packs containing 10 tablets each). Each white tablet has 'AN' embossed in a regular hexagon on one side.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:

Bayer plc
400 South Oak Way
Reading
RG2 6AD
United Kingdom

Manufacturers:

Bayer AG, Mullerstrasse 178, 13353 Berlin, Germany

or

Bayer Weimar GmbH & Co. KG, 99427 Weimar, Germany

This leaflet was last revised in August 2017.

Product licence number:

PL 00010/0553

Bayer

85996428

Pack details: Technical Specifications
Item: 85996428 Issue: 2
Artwork: LF Primolut N 5MG 7AB GB 02: 25981-4
colours: Black
version: 21/07/2017/01 Restricted Document dimension: 4.20 x 140 mm
Bayer AG
cost centre:
country: GB/7/BAG