Bayer plc

Bayer House
Strawberry Hill
Newbury
Berkshire RG14 1JA
United Kingdom

Telephone: **+44 (0)1635 563 000**
Facsimile: **+44 (0)1635 563 393**
Company Web Site: **http://www.bayer.co.uk**

Due to regulatory changes, the content of the following Patient Information Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes.

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.

Bayer

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 effects 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

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. Before you take Primolut N

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

or if you have:

- (or are recovering from) a **liver disease** and the blood tests show that your liver is not yet working normally
- certain types of **jaundice** (**Dubin-Johnson or Rotor syndrome)**.
- (or have ever had) **liver cancer.**

Blood Clots

Do not take Primolut N if you have **blood clots** in the legs, lungs, eyes or elsewhere, or have any medical condition which makes you more at risk of developing clots.

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)

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**)
- a rash known as **herpes gestationis** (also known as **pemphigoid gestationis**).

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

The doctor will take special care 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.
- you have an **intolerance to some types of sugar (galactose intolerance**, **Lapp lactase deficiency** or **glucose-galactose malabsorption**).

Tell your doctor before you take Primolut N if any of these applies to you.

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.

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. Although Primolut N is not an oral contraceptive, the risk of developing blood clots still exists. This risk may be higher if you:

- have had blood clots before
- suffer from severe diabetes with changes to the blood vessels
- suffer from sickle-cell anaemia

On rare occasions, the use of hormones has been associated with some types of liver cancer. These may lead to bleeding in the abdomen. Tell your doctor if you feel pain in the upper abdomen that does not go away.

Pregnancy

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.

Driving and using machines

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

3. How you take Primolut N

Take the tablets as instructed by your doctor.

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 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 do.

If you forget to take the tablets

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 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:

It is unusual for people to experience side effects when taking normal doses of Primolut N. Side effects that have been reported include:

- feeling slightly sick (nausea)
- worsening of epilepsy
- worsening of migraine
- skin problems

At very high doses, changes in the way that the liver works have been reported.

Tell your doctor if any side effect gets serious, or if you experience any effects not listed in this leaflet. You should also tell your doctor if you notice any changes in your health or general sense of well-being while you are taking Primolut N.

5. How to store Primolut N

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

Store in the original carton.

Do not use after the expiry date which is marked on both the outer container and on each blister strip of tablets.

Do not dispose of medicines in waste water or household rubbish. Any unused Primolut N tablets 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, maize starch and magnesium stearate (E572).

What's in 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:

Bayer plc
Bayer Schering Pharma
Bayer House
Strawberry Hill
Newbury
Berkshire
RG14 1JA
United Kingdom

Manufacturers:

Bayer Schering Pharma AG, Berlin, Germany
or
Schering GmBH & Co Produktions KG, Weimar, Germany

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