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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.



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.

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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 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

- 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. The ingredients are listed in section 6
- **pregnant** or if you think you might be pregnant
- **breastfeeding.**

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
- any **symptoms of a blood clot**, such as **chest pain, unexplained** and often **sudden shortness of breath** and/or **cough**
- any condition which makes you **more at risk of a blood clot** (*thrombosis*)
- ever suffered **migraine** with visual disturbance
- (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 tumours.**
- **diabetes** with damaged blood vessels.
- **any type of cancer which might be made worse by exposure to female sex hormones** (including breast cancer).
- problems with **genital bleeding** for which the cause is not yet known.
- 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.**

The doctor will take special care:

- 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 \geq 30kg/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 & 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 \geq 30kg/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.
- 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 \geq 30kg/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 about any other medicines that you are taking, or took recently. This includes any products you bought without a prescription.

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

Do not take Primolut N if you are pregnant or breastfeeding. 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 to 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

Like all medicines, Primolut N can have side effects – but 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 less than 1 in 10 people)

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

Uncommon side effects

(These may affect less than 1 in 100 people)

- Migraine

Rare side effects

(These may affect less than 1 in 1,000 people)

- Allergic reactions including skin rash or “hives”

Very rare side effects

(These may affect less than 1 in 10,000 people)

- Visual disturbances
- Difficulty in breathing

Other side effects

(Frequency unknown)

- Worsening of depression

- Dizziness
- Abdominal pain
- Jaundice
- Cholestasis

➔ **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.

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