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The product code for this leaflet is: PL 00053/5033R

Primolut N

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PATIENT INSTRUCTION LEAFLET

PRIMOLUT® N

Please read this leaflet carefully before you start your treatment.

A guide to using Primolut N

This leaflet only provides a summary of the information available on Primolut N. If you have any questions or are not sure about anything ask your doctor or pharmacist.

The reason why you can only get this medicine with a doctor's prescription is that its use needs medical supervision.

Please tell your doctor if you have any doubts or worries about using this medicine either before you start or while you are using it.

The name of your medicine is: Primolut N (norethisterone)

What does your medicine contain?

Each tablet contains 5mg norethisterone.

Primolut N also contains the following inactive ingredients:

lactose
maize starch
magnesium stearate (E 572)

Your medicine is supplied in a box containing 3 foil blister packs. Each pack contains 10 tablets.

Primolut N contains norethisterone which is a progestogen (a female hormone) and it is mainly used to treat a number of disorders of the menstrual cycle.

The product licence is held by:

Schering Health Care Ltd.
The Brow
Burgess Hill
West Sussex
RH15 9NE

Product licence number: 0053/5033R

Primolut N is manufactured by

Schering AG
Berlin
Germany

or

Schering GmbH & Co Produktions KG
Weimar
Germany

Uses

This medicine is used to treat irregular, painful or heavy periods. It is also used in the treatment of endometriosis (presence of tissue from the lining of the womb in places where it is not normally found), premenstrual syndrome (also known as premenstrual tension, PMS or PMT), and to delay periods.

Reasons for not taking Primolut N

You should not take this medicine if any of the following apply to you:

- you are pregnant or think you may be pregnant.
- you have (or are recovering from) a liver disease, and the blood tests of liver function have not yet returned to normal.
- you have certain types of jaundice (Dubin-Johnson or Rotor syndromes).
- you have (or have ever had) liver tumours.
- 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.
- you have an allergy to norethisterone or any of the other ingredients.

Do not take this medicine if you have had any of these 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).

What you should know before taking Primolut N

Before taking this medicine the doctor will make sure that you are not pregnant.

This medicine can produce changes in blood sugar levels. If you are a diabetic your doctor will check blood sugar levels before and regularly during treatment.

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, including cerebral infarction (stroke) and myocardial infarction (heart attack) and subarachnoid haemorrhage (bleeding into the brain) has been reported to be slightly greater in women taking the combined oral contraceptive pill than for non-users. People do not always fully recover from such blood clots, and very rarely they are 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.
- you suffer from severe diabetes with changes to the blood vessels.
- you suffer from sickle-cell anaemia.

On rare occasions, the use of hormonal substances such as the one in Primolut N has been associated with some forms of liver tumour. Liver tumours may lead to bleeding in the abdomen. Therefore if you feel pain in the upper abdomen that does not go away, tell your doctor.

Important information about some of the ingredients of Primolut N

If you have an intolerance to some sugars contact your doctor before taking Primolut N as it contains the sugar lactose.

Reasons for stopping Primolut N immediately

You should stop taking this medicine and should 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, speech, sense of smell, taste or touch
- symptoms of blood clot formation or symptoms of an inflammation of 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
- surgery . You must stop taking Primolut N six weeks before any planned major operation, if you are having any surgery to the legs, or medical treatment for varicose veins
- you are immobilised for a long time (e.g. bed-rest after an accident or operation or you have a plaster cast on a broken leg).

Primolut N must also be stopped at once if you become pregnant, or if you develop jaundice or other liver problems, or itching (pruritus), or if your doctor finds your blood pressure to be significantly raised.

How to take Primolut N

Take the tablets as instructed by your doctor. There are several different dosage schemes for Primolut N. The number of tablets that you have to take and the number of days per month that you have to take tablets on, will depend on what this medicine has been prescribed for. A usual dosage would be 2-3 tablets each day. For some conditions Primolut N has to be taken everyday. If you are not sure about the number of tablets that you have to take or when to take the tablets you must ask your doctor or pharmacist. The tablets should be swallowed whole with a drink of water.

Remember to return any unused tablets to your pharmacist.

Overdosage

There have been no reports of ill-effects from overdosage. You should consult your doctor who will be able to advise you what action, if any, is necessary.

What to do if you miss a dose

If you have forgotten to take your medicine do not make up for it by taking extra tablets. When you remember, take the next prescribed dose and continue with the treatment. If you are concerned, contact your doctor or pharmacist.

Side-effects

When taken at normal doses, side effects are rare with Primolut N. Side effects that have been reported include slight nausea, a worsening of epilepsy and migraine.

Skin problems also may occur.

At much higher doses, changes in the normal function of the liver have been reported.

Should you notice any changes in your health or general sense of well-being during your treatment with Primolut N you should discuss these with your doctor.

Expiry date: The expiry date is printed on the pack. Do not use after this date.

Storage: Keep out of the reach of children.

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