Take special care with Primolut N

If any of the diseases or conditions listed below appears or worsens when you take Primolut N tablets, contact your doctor. He or she will discuss with you about the benefits and disadvantages of starting or continuing the use of Primolut N, and your doctor will also decide whether your health should be closely monitored,

• if you have diabetes
• if you have a history of thrombosis (for more information, see below)
• if you have or have had liver spots (golden brown skin pigmentation especially on the face); avoid overexposure to sunlight and ultraviolet radiation
• if you have had depression.

Contact your doctor if any of the above conditions appears for the first time, recurs or worsens while you are using Primolut N.

Primolut N and thrombosis

Research results indicate that the use of oral contraceptives containing estrogen and progestin increases the risk of developing a blood clot compared with women who are not using any oral contraceptives.

It is generally acknowledged that the risk of thrombosis increases

• with age
• if you are overweight
• if you are scheduled for surgery, need to be immobilized for a long time or have had a serious accident.

If you know you are going to a hospital or surgery, it is important that you tell your doctor that you are using Primolut N since the treatment may have to be stopped. Your doctor will also tell you when you can start using Primolut N again when you are back on your feet.

In rare single cases thrombosis may cause serious permanent disability or may even be fatal.
• If you notice any signs of thrombosis, stop using Primolut N and contact your doctor immediately. (See also section “When to contact your doctor?”.)

Prilomol N and cancer
In rare cases benign liver tumors, and even more rarely malignant liver tumors, have been reported in users of hormone preparations similar to Primolut N. These tumors may lead to internal bleeding.

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

WHEN TO CONTACT YOUR DOCTOR?

Regular check-ups
• When you are using Primolut N, your doctor will tell you when to come for regular check-ups.

Contact your doctor as soon as possible if
• you notice any changes in your health, especially if the changes are related to issues mentioned in this package leaflet (see also sections “Do not use Primolut N” and “Take special care with Primolut N” and the following section on blood thrombosis; do not forget the factors related to your immediate family)
• you intend to use other medications (see also section “Taking other medicines”)
• you are immobilized for a longer period of time or have surgery scheduled (contact your doctor at least six weeks in advance)
• you have unusual, heavy vaginal bleeding.

Stop taking Primolut N and contact your doctor immediately if you notice any signs of thrombosis, such as:
• a stabbing pain on breathing or coughing without a clear reason
• a feeling of pain and pressure in the chest; the pain may radiate to your left arm
• Breathlessness
• more and more frequent occurrence of exceptionally severe and prolonged headache or occurrence for the first time of migrainous headache or sudden perceptual disorder (e.g. disturbances in vision or hearing)
• partial or complete loss of vision, or double vision

• slurring or speech disability
• sudden changes in your hearing, sense of smell, or taste
• dizziness or fainting
• weakness or numbness in some part of the body
• Severe pain or swelling in either of your legs.

Stop using Primolut N and contact your doctor immediately also if
• you have jaundice (yellowish skin and whites of your eyes; these can be signs of a liver inflammation)
• you have generalized severe itching
• you have high blood pressure
• you are pregnant.

The situations and symptoms mentioned above are described and explained in more detail elsewhere in this leaflet.

Taking other medicines
Some medicines and herbal products may reduce the efficacy of Primolut N by increasing the elimination of the active ingredient from the body. These include medicines used for the treatment of epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbamazepine) and tuberculosis (e.g. rifambicin, rifabutin), antibiotics used for the treatment of infectious diseases (e.g. griseofulvin) and herbal products containing St. John’s wort (used originally in the treatment of depression). Primolut N may also affect the efficacy of other medicines (e.g. medicines containing cyclosporine).

• Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Ask your doctor for advice before using any medicine.

Laboratory tests
If you are having a blood test, tell the doctor or laboratory personnel that you are using Primolut N since it may affect the results of some tests.

Using Primolut N with food and drink
Tablets are meant to be swallowed whole with liquid.

Pregnancy and lactation
Do not use Primolut N if you are pregnant or suspect that you may be pregnant.
Primolut N is not recommended during pregnancy since a small amount of the active ingredient may be excreted in breast milk.

Driving and using machines
No studies have been conducted on how the product affects the ability to drive and use machines.

Important information about some of the ingredients in Primolut N
If you have been told by your doctor that you have some sugar intolerance, talk to your doctor before taking this medicine.

3. HOW TO USE PRIMOLUT N?
Take the tablets whole with liquid.
If you have sexual intercourse, you should use non-hormonal contraception (e.g. condoms) instead of oral contraceptives. If you suspect that you have become pregnant despite using contraception, stop using Primolut N until your doctor has examined you.
Primolut N is used individually according to the directions of your doctor. Always follow the doctor’s dosage instructions.
These are the recommended doses:

**Bleeding disorders**
Take 1 Primolut N tablet 3 times daily for 10 days. This will in most cases stop uterine bleeding with no associated organ damage within 1–3 days.

To achieve the therapeutic effect, Primolut N tablets must be taken regularly during the full 10-day treatment period even if bleeding stops before that.

About 2–4 days after the discontinuation of treatment, withdrawal bleeding will occur resembling normal menstruation in intensity and duration.

Occasionally slight bleeding may occur even after the initial arrest of bleeding. Do not stop or interrupt tablet taking even if this happens.

If the bleeding continues despite the fact that you have taken the tablets correctly, the possibility of an organic or extragenital cause should be considered. This kind of cause most often requires other treatment procedures. This also applies if heavy bleeding recurs after the arrest of bleeding during continued tablet taking.

• **Should this happen, contact your doctor.**
Your doctor may decide that you should take Primolut N tablet preventively (in connection with an anovulatory cycle) to stop reoccurrence of bleeding disorders: 1 tablet 1–2 times daily from the 16th to the 25th day of the cycle (1st day of cycle = 1st day of bleeding).

Withdrawal bleeding starts a few days after the medication is stopped.

**Absence of menstruation (primary or secondary amenorrhea)**
Your doctor will prescribe you estrogen (for 14 days, for example) before you start treatment with Primolut N. Thereafter take 1 Primolut N tablet 1–2 times daily for 10 days.

Withdrawal bleeding starts a few days after the tablet taking is stopped.

If adequate endogenous estrogen production has been achieved, administration of estrogen can be stopped and Primolut N can be used at a dosage of 1 tablet 2 times daily between the 16th and 25th day of the cycle in an attempt to induce cycle bleeding.

**Premenstrual syndrome, mastopathy**
Premenstrual symptoms such as headache, depressive moods, water retention and breast tenderness can be relieved at a dosage of 1 tablet 1–3 times daily during the progestational phase of the cycle.

**Timing of menstruation**
Primolut N tablets can be used to postpone menstruation but only in such cycles when there is no possibility of pregnancy.

Take 1 Primolut N tablet 2–3 times daily for 10–14 days beginning about 3 days before the expected menstruation. Bleeding will start 2–3 days after the medication is stopped.

**Endometriosis**
Treatment is commenced between the 1st and 5th day of the cycle at a dosage of 1 Primolut N tablet twice daily. If spotting appears, the dose is increased to 2 tablet twice daily. When the bleeding ceases, the initial dosage can be resumed. The treatment is continued for at least 4–6 months. During the treatment, there will usually be no ovulation nor menstruation.
Withdrawal bleeding will start once the hormone treatment is stopped.

**If you take more Primolut N than you should:**
Do not take more Primolut N tablets than your doctor has ordered.

There have been no reports of serious side effects from taking too many Primolut N tablets.

If you have taken several tablets at one time, this may cause nausea, vomiting or vaginal bleeding. If you have taken too many tablets or notice that a child has taken Primolut N tablets, ask your doctor for advice.

**If you forget to take Primolut N:**
The effect of Primolut N may be reduced if you forget to take a tablet according to instructions. You should take only the last tablet you have forgotten as soon as possible and then continue with the tablet taking at the usual time the next day.

Do not take a double dose to make up for forgotten tablets.

**If you stop taking Primolut N:**
Stopping the use of Primolut N does not cause any specific symptoms but it is possible that the original symptoms will return.

4. **POSSIBLE SIDE EFFECTS**
Like all medicines, Primolut N can have side effects, although not everybody gets them.

• **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.**

Side effects are more common during the first months of treatment and disappear gradually when the treatment is continued. In addition to the side effects mentioned in “Take special care with Primolut N”, the following side effects have been reported in connection with the use of Primolut N but their causal relationship with the product has not always been established.

Here is a list of side effects according to their frequency:

<table>
<thead>
<tr>
<th>Very common:</th>
<th>10 or more in 100 patients will probably get these:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• uterine bleeding / vaginal bleeding, including spotting*</td>
</tr>
<tr>
<td></td>
<td>• hypomenorrhea (scanty menstruation).*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Common:</th>
<th>1–10 in 100 patients will probably get these:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• headache</td>
</tr>
<tr>
<td></td>
<td>• nausea</td>
</tr>
<tr>
<td></td>
<td>• absence of menstruation (amenorrhea)</td>
</tr>
<tr>
<td></td>
<td>• water retention.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Uncommon:</th>
<th>1–10 in 1000 patients will probably get these:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• migraine.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Rare:</th>
<th>1–10 in 10,000 patients will probably get these:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• hypersensitivity reactions</td>
</tr>
<tr>
<td></td>
<td>• nettle rash</td>
</tr>
<tr>
<td></td>
<td>• rash</td>
</tr>
<tr>
<td></td>
<td>• breast tenderness, changes in libido.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Very rare:</th>
<th>Less than 1 in 10,000 patients will probably get these:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• visual disturbances</td>
</tr>
<tr>
<td></td>
<td>• shortness of breath.</td>
</tr>
</tbody>
</table>

* In the endometriosis indication

5. **STORAGE INSTRUCTIONS**
Keep out of the reach and sight of children.

Do not use after the expiry date marked on the package.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Store below 30°C.

6. **FURTHER INFORMATION**
What does Primolut N contain

**Composition**
Primolut N tablets contain 5 mg of norethisterone as active substance.

**Excipients:** Lactose monohydrate 70 mg, maize starch, magnesium stearate.

**What Primolut N looks like and contents of the pack:**
White, cross-scored tablets on one side with an emblem ‘AN’ in a hexagon on the other side.

30 tablets in a blister pack (PVC/Aluminum).

**Manufacturer**
Schering GmbH und Co. Produktions KG, Weimar, Germany

This leaflet was compiled on May 7, 2008.