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PHARMACODE

Package leaflet: Information for the user

Norethisterone 5mg Tablets

norethisterone

Your medicine is called Norethisterone 5mg Tablets, but it will be referred to as Norethisterone throughout this leaflet.

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 Norethisterone is and what it is used for
2. What you need to know before you take Norethisterone
3. How to take Norethisterone
4. Possible side effects
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1. What Norethisterone is and what it is used for

Norethisterone contains norethisterone, which belongs to a group of medicines called *progestogens*, which are female hormones.

Norethisterone 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 Norethisterone

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 Norethisterone

- 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**
- 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

Do not use Norethisterone if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir (see also in section "Other medicines and Norethisterone").

In addition, do not take Norethisterone 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 Norethisterone**.

Warnings and precautions

- Talk to your doctor or pharmacist before taking Norethisterone
- If you **smoke**
 - If you have **diabetes** (metabolic disease with elevated blood sugar levels). Norethisterone 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 Norethisterone")
 - 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 norethisterone
 - 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). High blood levels of fatty substances have been associated with an increased risk of developing pancreatitis (inflammation of pancreas)
 - 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 Norethisterone"

Tell your doctor before you take norethisterone if any of these apply to you. Also tell your doctor if any of these conditions develop or worsen while you are taking norethisterone, because you may need to stop taking it.

Norethisterone and blood clots

The main ingredient in norethisterone (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 norethisterone 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 norethisterone may add to this risk so it may not be suitable for you. To reduce the risk of blood clots, treatment with norethisterone 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 norethisterone until your doctor says you can.

Norethisterone 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 ≥ 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 tumors, 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 norethisterone.

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Other medicines and Norethisterone

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

- Some medicines
- Can have an influence on the blood levels of norethisterone
 - Can make it **less effective**
 - Can cause unexpected bleeding

These include:

- Medicines used for the treatment of
 - Epilepsy (e.g., primidone, phenytoin, barbiturates, carbamazepine, oxcarbamazepine, topiramate, felbamate)
 - Tuberculosis (e.g., rifampicin)
 - HIV and hepatitis C virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors, e.g., ritonavir, nevirapine, efavirenz)
 - Fungal infections (griseofulvin, azole antifungals, e.g., itraconazole, voriconazole, fluconazole)
 - Bacterial infections (macrolide antibiotics, e.g., clarithromycin, erythromycin)
 - Certain heart diseases, high blood pressure (calcium channel blockers, e.g., verapamil, diltiazem)
 - Arthritis, arthrosis (etoricoxib)
- High blood pressure in the blood vessels in the lung (bosentan)
- The herbal remedy St. John's wort (primarily used for the treatment of depressive moods)
- Grapefruit juice

Norethisterone may **influence the effect** of other medicines, e.g.,

- Medicines containing ciclosporine
 - The anti-epileptic lamotrigine (this could lead to an increased frequency of seizures)
 - Theophylline (used to treat breathing problems)
 - Tizanidine (used to treat muscle pain and/or muscle cramps)
- Do not use norethisterone if you have Hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir as this may cause increases in liver function blood test results (increase in ALT liver enzyme). Norethisterone can be restarted approximately 2 weeks after completion of this treatment. See section "Do not use Norethisterone".

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

Other things you should know

Once you have finished taking a course of norethisterone, 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 norethisterone 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

Norethisterone is unlikely to affect your ability to drive or use machines.

Norethisterone contains Maize starch

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 Norethisterone

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 norethisterone. A common dosage would be 2-3 tablets each day. For some conditions, norethisterone 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 Norethisterone 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 Norethisterone

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 Norethisterone immediately

- Stop taking norethisterone 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

Norethisterone 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 Norethisterone are listed below according to the frequency with which they occur.

Very common (*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 (*These may affect up to 1 in 10 people*)

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

Uncommon (*These may affect up to 1 in 100 people*)

- Migraine

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

- Allergic reactions including skin rash or "hives"

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

- Visual disturbances
- Difficulty in breathing

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 via the Yellow Card Scheme at: <http://www.mhra.gov.uk/yellowcard> or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Norethisterone

Keep this medicine out of the sight and reach of children. This medicinal product does not require any special storage conditions. Do not take the medicine after the expiry date which is stated on the carton and bottle labels 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 Norethisterone contains

Each tablet contains 5mg of norethisterone. The other ingredients are Microcrystalline cellulose, Maize starch, Ethyl cellulose, Ethanol and Magnesium stearate. See section 2 for further excipient information on Norethisterone contains Maize starch.

What Norethisterone looks like and contents of the pack
White to off white, round shaped, flat tablets, beveled edge debossed "L" on one side and "12" on another side.

The tablets are available in aluminium/PVC /PVDC blister packs of 30.

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