

Norethisterone 5mg tablets

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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 tablets are and what they are used for
- 2** What you need to know before you take Norethisterone tablets
- 3** How to take Norethisterone tablets
- 4** Possible side effects
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1 What Norethisterone tablets are and what they are used for

Norethisterone tablets belong to a group of medicines called progestogens. These work by acting on receptors in the body to mimic or exaggerate the effects of the natural hormone, progesterone.

Norethisterone tablets may be used to treat:

- or prevent abnormal or unexpected bleeding from the uterus
- the symptoms of pre-menstrual syndrome which occur before a period including breast pain, headache, migraine, water retention and mood disturbances
- painful or heavy periods
- endometriosis
- certain types of breast cancer.

The tablets can also be used to stop periods.

2 What you need to know before you take Norethisterone tablets

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 tablets and **tell** your doctor if you have:

- **if you are allergic** to norethisterone or any of the other ingredients of this medicine (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 tumors.**
 - **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 Norethisterone tablets 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**)

Warnings and precautions

Talk to your doctor or pharmacist before taking Norethisterone tablets if you:

- smoke
- have **diabetes**. Norethisterone tablets 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.

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- are overweight (**BMI** ≥ 30 kg/m²)
- have **high blood pressure**
- have a **heart valve disorder** or a certain **heart rhythm disorder** (heart problems)
- 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
- suffer from **migraine, asthma, or kidney problems**
- suffer from **epilepsy** (see "Other medicines and Norethisterone tablets")
- have an **inflammation of your veins** (superficial phlebitis)
- have **varicose veins**
- have anyone in your immediate family who has had **breast cancer**
- 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 tablets.
- have previously suffered from **depression.**
- or someone in your close family has ever had **high blood levels of cholesterol or triglycerides** (fatty substances)
- have a disease of the liver or gall bladder
- have certain rare medical conditions such as **systemic lupus erythematosus (SLE), sickle cell disease, Crohn's disease or ulcerative colitis**
- have **haemolytic uremic syndrome (HUS)**
- 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**)
- 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
- have an **intolerance to some types of sugar (galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption)**
- are using other medications as mentioned in "Other Medicines & Norethisterone tablets".

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

Norethisterone tablets 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 tablets 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 tablets may add to this risk so it may not be suitable for you.

To reduce the risk of blood clots, treatment with Norethisterone tablets 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 tablets until your doctor says you can.

Norethisterone tablets 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.

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- 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 Norethisterone tablets.

Tests

If you go to a different doctor than the one who has prescribed you this medicine, or go to the hospital, let them know that you are taking Norethisterone tablets as they may affect certain tests.

Children and adolescents

Not recommended.

Other medicines and Norethisterone tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Especially:

- other hormonal products (oestrogens or progestogens)
- medicines used to treat epilepsy (e.g. phenobarbital, phenytoin, carbamazepine)
- medicines used to treat infections (e.g. rifampicin, nevirapine, tetracyclines, ampicillin, oxacillin, co-trimoxazole, ritonavir, neflavinir)
- St. John's Wort (*hypericum perforatum*) (a herbal remedy)
- aminoglutethimide
- ciclosporin (to prevent transplant rejection)
- other medicines which can also cause fluid retention such as anti-inflammatory medicines (e.g. ibuprofen) or vasodilators

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before taking this medicine as **you should not take these tablets**.

Driving and using machines

Norethisterone tablets may make you feel dizzy, drowsy or affect your vision. Make sure you are not affected before you drive or operate machinery.

Norethisterone tablets and lactose

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains a type of sugar called lactose.

3 How to take Norethisterone tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

This medicine should be taken for as long as your doctor tells you to. If you finish the course of Norethisterone tablets you will usually have a menstrual bleed 2-3 days after the last tablet. If you do not have a period you must make sure you are not pregnant before taking more.

Day one of the cycle is the first day of your period.

The recommended dose is:

Adult

- **Abnormal bleeding** – 1 tablet three times a day for 10 days. Bleeding usually stops within 1-3 days. A period usually starts 2-4 days after stopping treatment.
- **Prevention of abnormal bleeding** – 1 tablet twice a day from the 19th - 26th day of the cycle.
- **Premenstrual syndrome** - 2 to 3 tablets a day from the 19th - 26th day of the cycle. You will normally be treated for several months.
- **Stopping a period** - 1 tablet three times a day starting three days before the expected beginning of the period. Your period should occur 2-3 days after you have stopped taking the medicine.
- **Painful periods** - 1 tablet three times a day for 20 days starting on the 5th day of the cycle. You will usually be treated for 3-4 cycles.
- **Heavy periods** - 1 tablet two to three times a day from the 19th - 26th day of the cycle.
- **Endometriosis** - 2 tablets a day starting on the 5th day of your cycle. If you continue having small bleeds ("spotting"), the dosage may be increased to 4 to 5 tablets a day. Once bleeding has stopped the dosage may be reduced. You will usually be treated continuously for 4-6 months or longer.
- **Breast cancer** - 8 tablets a day, the dosage may be increased to 12 tablets a day.

Elderly - Not recommended.

Swallow the tablets with water.

If you take more Norethisterone tablets than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include feeling or being sick, breast enlargement or vaginal bleeding.

If you forget to take Norethisterone tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

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If you stop taking Norethisterone tablets

Talk to your doctor before you stop taking the tablets and follow their advice.

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.

Stop taking Norethisterone tablets and contact your doctor immediately if you develop the following:

- a rise in blood pressure
- jaundice (yellowing of the skin or whites of the eyes)
- migraine-type headaches
- signs of severe hypersensitivity (anaphylaxis): e.g. swelling of the mouth, tongue, face, throat, difficulty breathing, wheezing, severe skin rash, itch, redness
- if you become pregnant
- unusually bad headache
- severe itching (pruritus)
- other liver problems and signs e.g. abdominal pain, nausea, vomiting, tiredness, dark brown urine
- any sudden changes in eyesight, hearing or speech
- any changes in sense of smell or touch
- **Hypersensitivity reactions:** severe allergic reaction including skin rash, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing

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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

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- **Genital and urinary:** breakthrough bleeding, spotting, absence of bleeding, abnormal bleeding (irregular; increase or decrease), alterations of cervical secretions, cervical erosions, prolonged anovulation (not producing an egg), over production of breast milk, breast pain and tenderness
- **Gastrointestinal:** feeling or being sick
- **Heart:** blood clotting disorders (in the lower limbs, lungs or eye), increased blood pressure, inflammation of the veins
- **Liver:** changes in liver function
- **Nervous system:** depression, headache, dizziness, tiredness, difficulty in sleeping, nervousness, drowsiness, loss of concentration, vision disorders and intolerance to contact lenses
- **Metabolic and nutritional:** altered blood levels of cholesterol, changes in insulin and glucose control, diabetic cataract, worsening of diabetes mellitus, sugar in the urine
- **Skin:** acne, hair growth (especially on the top lip or chin), hair loss, rash which may be itchy, worsening of existing skin conditions
- **Other:** fluid retention, bloating, weight gain, fever, change in appetite, deepening of the voice, changes in the sex drive

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Norethisterone tablets

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

Do not use this medicine after the expiry date stated on the carton. The expiry date refers to the last day of that month.

Do not store this medicine above 25°C and keep in the original packaging.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What Norethisterone tablets contain

- The active substance is Norethisterone. Each tablet contains 5mg of the active ingredient.
- The other ingredients are lactose, maize starch, magnesium stearate.

What Norethisterone tablets look like and contents of the pack

Norethisterone are white circular uncoated tablets.

Pack sizes are 30 tablets.

Marketing Authorisation Holder

Actavis, Barnstaple, EX32 8NS, UK

Manufacturer

CP Pharmaceuticals Ltd, Wrexham, LL13 9UF

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