

PACKAGE LEAFLET: INFORMATION FOR THE USER

Norethisterone 5mg Tablets
Norethisterone



Read all of this leaflet carefully before you start using 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.

The name of your medicine is Norethisterone 5mg Tablets. In the rest of this leaflet it is called Norethisterone Tablets.

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
5. How to store Norethisterone Tablets
6. Contents of the pack and other information

1. What Norethisterone Tablets are and what they are used for

Norethisterone Tablets is one of a group of medicines called 'Progestogens'. Progestogens are similar to the natural female hormone progesterone. Norethisterone Tablets contains the progestogen called norethisterone as the active ingredient. Norethisterone Tablets has many uses.

You can take Norethisterone Tablets to treat or manage:

- Heavy periods
- Painful periods
- Irregular periods or periods that are more frequent than normal
- Premenstrual tension (PMT)
- Endometriosis (where tissue from your womb is found outside your womb)
- Breast cancer.

Your doctor may also prescribe Norethisterone Tablets if you want to delay your next period.

2. What you need to know before you take Norethisterone Tablets

Norethisterone Tablets may not be suitable for all women. Please read the following list carefully to see if any of these apply to you. Consult your doctor if you are not sure.

Do not take Norethisterone Tablets:

- if you are allergic to norethisterone, or other similar hormone medicines, or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant or think you might be pregnant. Your doctor may give you a pregnancy test before starting treatment or if you miss a period during treatment
- if you have now or have ever had any vaginal bleeding (not a period) for which your doctor could not find a cause.
- if you or a member of your family have ever had a problem with blood clots, including deep vein thrombosis (DVT).
- if you have now or have had in the past, a heart attack or angina.
- if you have liver problems.
- if you have ever had a pregnancy where you had jaundice, or an itchy rash known as pemphigoid gestationis. This rash appears as small blisters on your abdomen.
- if you have severe generalised itching all over your body (pruritis)
- if you have a condition known as porphyria (a rare inherited blood disease).

Warnings and precautions

Talk to your doctor or pharmacist before taking Norethisterone Tablets if you have any of the following conditions. This will help them decide if Norethisterone Tablets is suitable for you:

- Epilepsy
- Migraine headaches
- Asthma
- Heart problems
- Kidney problems.

Risk of Venous Thromboembolism (VTE)

All women have a small chance of having a blood clot in the veins of the leg, in the lung or other part of the body. The chances of getting a clot are very slightly higher if you are taking a hormone medicine like Norethisterone Tablets. You are more likely to get a clot whether or not you are taking Norethisterone Tablets if you:

- are very overweight
- have systemic lupus erythematosus. (This is a condition where the immune system attacks healthy tissues, typically causing symptoms such as painful joints and muscles, tiredness, fever and rashes).
- have had a blood clot in the veins or lungs before
- have relatives who have had blood clots
- are unable to move for long periods of time (for example after an operation)
- have a serious injury or have major surgery
- have a history of repeated miscarriage.

Tell your doctor if you have just had an operation or if you are going to have an operation while taking Norethisterone Tablets. Section 4 of this leaflet ('Possible side effects') also has more information on the warning signs of blood clots

Other medicines and Norethisterone Tablets

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

This includes the following medicines, as the effect of Norethisterone Tablets may be altered when they are taken at the same time:

- Medicines to treat epilepsy (e.g. phenytoin, carbamazepine)
- Antibiotic medicines to treat an infection (e.g. tetracyclines, rifampicin, co-trimoxazole)
- Antiviral medicines to treat HIV (e.g. ritonavir, nelfinavir)

- Anticancer medicines
- Herbal preparations containing St John's wort (Hypericum perforatum)
- Aminoglutethimide, sometimes used in Cushing's Syndrome.
- Ciclosporin (for suppressing the immune system)
- Non-steroidal anti-inflammatory drugs (NSAIDs) for treating pain and inflammation
- Medicines for high blood pressure.

Norethisterone Tablets can also interfere with some laboratory tests, so tell your doctor if you are having any blood tests or hospital investigations.

Tell your doctor or pharmacist if you are taking any other medicines not listed above, including those bought without a prescription.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

Norethisterone Tablets must not be taken if you are pregnant as hormonal medicines can affect the developing baby. It is important you use some form of contraception (e.g. a condom) while taking Norethisterone Tablets, as it is not a contraceptive.

Breast-feeding

If you are breast-feeding, ask your doctor for advice before taking this medicine, so they can advise whether you should use an alternative method of feeding your baby.

Driving and using machines

No effect on the ability to drive or use machinery has been seen with Norethisterone Tablets.

Norethisterone Tablets contains lactose

Lactose is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Norethisterone Tablets

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

The recommended dose will depend on the condition you are being treated for. This information can also be found on the label on the box the tablets come in. The following information will help you see what the usual dose is for a particular problem.

Taking Norethisterone Tablets for heavy bleeding and other period problems -

You will usually take 1 tablet 3 times a day (15 mg) for 10 days. A few days after you stop taking the tablets you will usually have bleeding like a period. To stop your periods causing problems again, your doctor may tell you to take Norethisterone Tablets for a few days after your next two periods. You will probably take 1 tablet twice a day (10 mg) for 8 days. You will need to start taking these tablets 19 days after your last period began.

Taking Norethisterone Tablets for premenstrual tension -

You will usually take one 5 mg tablet a day for 10 days, starting 16 days after your last period began.

Taking Norethisterone Tablets for endometriosis -

You will usually take 1 tablet 3 times (15 mg) a day for at least 6 months. If you have any irregular bleeding or spotting, your doctor may increase the dose to 4 or 5 tablets (20-25 mg) a day until this bleeding stops.

Taking Norethisterone Tablets for breast cancer - You will usually take 8 tablets (40 mg) a day. Your doctor may increase this to 12 tablets (60 mg).

Taking Norethisterone Tablets to delay your periods - You will usually take 1 tablet 3 times (15 mg) a day. You need to start taking the tablets 3 days before your period is due to start. Your period will usually start within 3 days of finishing the tablets.

If you do not have a period after you finish a course of Norethisterone Tablets, check with your doctor in case you are pregnant.

If you take more Norethisterone Tablets than you should:

If you take more Norethisterone Tablets than you should, contact your doctor straight away.

If you forget to take Norethisterone Tablets

Take the tablet as soon as you remember, and carry on taking the tablets at the normal times. Do not take a double dose to make up for a forgotten dose.

If you stop taking Norethisterone Tablets

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 Tablets treatment immediately

Very rarely, Norethisterone Tablets may cause a severe allergic reaction which can be life-threatening in some cases. You can get some or all of the following symptoms:

- wheezing
- difficulty breathing
- feeling faint
- swelling of the face or tongue
- swelling of the hands and feet
- intense itchy skin rash.

If you think you are reacting badly to the medicine, get emergency medical help immediately.

The following symptoms could be warning signs of thrombosis (a blood clot) which will need urgent treatment:

Symptoms of a blood clot in the lungs:

- Sudden, severe, sharp pain in your chest
- Coughing up blood
- You suddenly become short of breath
- Your heart beats more rapidly

Symptoms of a blood clot in the brain ('a stroke'):

- You have an unusually severe or long headache
- Your sight is affected in any way
- You find it difficult to speak
- You collapse or faint
- Any part of your body feels weak or numb

Symptoms of a deep-vein thrombosis (DVT):

- You have severe pain, tenderness or swelling in your calf, ankle or foot
- You have purple discolouration of the skin of the leg or the skin becomes red and warm to touch

If you get any of these symptoms, you should **stop taking** the tablets and see your doctor **immediately**.

Reasons for seeking medical advice during treatment

It is important to see your doctor straightaway if you get:

- Yellowing of the skin or whites of the eyes (jaundice)

- Migraine headache for the very first time
- Your doctor may also decide to stop treatment if your blood pressure gets too high.

Other side effects

You can also get the following side effects with medicines like Norethisterone Tablets:

Effects on the reproductive system and breasts: bleeding and spotting between periods, lack of periods (amenorrhoea), unexpected or unusual vaginal bleeding, changes in discharge from the cervix, cervical erosions (this may be seen when you have a smear test), cycles where you don't ovulate (anovulation), breast pain and tenderness, a milky discharge from the breast when not pregnant or breastfeeding (galactorrhoea).

Effects on the nervous system:

headache, depression, dizziness, fatigue, difficulty sleeping, confusion, nervousness, a feeling of intense happiness (euphoria), feeling sleepy, loss of concentration, vision problems.

Effects on the stomach and intestines:

feeling or being sick, constipation, diarrhoea, dry mouth.

Effects on the liver: disturbed liver function, yellowing of the skin or whites of the eyes.

Effects on your metabolism: altered fat levels in the blood, alteration of blood sugar levels, increased levels of insulin between meals and existing diabetes getting worse, decreased tolerance to some sugars like glucose, adrenergic-like effects (e.g. fine hand tremors, sweating, cramps in the calves at night), effects on the adrenal glands (e.g. Cushingoid syndrome), cloudy vision, sugar in your urine.

Effects on your heart and circulation: blood clots, including clots in the lung, and swelling in the veins due to blood clots, stroke, heart attacks, congestive heart failure, increased blood pressure, feeling your heartbeat, clots in the blood vessels of the retina (this causes visual problems), heart beating faster (tachycardia).

Effects on your skin and hair: acne, increase in body or facial hair, hair loss, itching, rash, hives.

Miscellaneous: fluid retention and swelling of hands and ankles, bloating, weight gain, raised temperature, change in appetite, changes in sex drive, fatigue, increase in calcium (seen in blood tests).

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 national reporting systems listed below:

United Kingdom

Yellow Card Scheme
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Malta

ADR Reporting

Website:

www.medicinesauthority.gov.mt/adrportal

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 which is stated on the carton. The expiry date refers to the last day of that month.

- Do not use this medicine if you notice any signs of deterioration such as discolouration (they should be white).
- Norethisterone Tablets should not be

stored above 25°C. The tablets should be kept in their original container, in order to protect from light.

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 Tablets contain
The active substance is norethisterone. Each tablet contains 5mg.

The other ingredients are lactose, maize starch and magnesium stearate.

What Norethisterone Tablets look like and contents of the pack

Norethisterone Tablets are round, white, uncoated tablets with "NE 5" on one side and a break line on the other.

Norethisterone Tablets are available in blister packs of 30, 72 and 180 tablets in aluminium foil. Not all pack sizes may be marketed.

Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge **0800 198 5000 (UK Only)**

Please be ready to give the following information:

Product Name	Reference Number
Norethisterone 5mg Tablets	29831/0152

This is a service provided by the Royal National Institute of Blind People.

For Malta please call +44 1978 661261.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder in UK: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Marketing Authorisation Holder in Malta: Pinewood Laboratories Ltd., Ballymacarby, Clonmel, Co. Tipperary, Ireland.

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

This leaflet was revised in 02/2020.

This medicinal product is authorised in the Member States of the EEA under the following names:

UK: Norethisterone 5mg Tablets

Malta: Norethisterone 5mg Tablets

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