

PACKAGE LEAFLET: INFORMATION FOR THE USER

Norethisterone 5mg Tablets
Norethisterone



Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

In this leaflet:

1. What Norethisterone Tablets are and what they are used for
2. Before you take Norethisterone Tablets
3. How to take Norethisterone Tablets
4. Possible side effects
5. How to store Norethisterone Tablets
6. Further information

1. WHAT NORETHISTERONE TABLETS ARE AND WHAT THEY ARE USED FOR

The active ingredient in Norethisterone Tablets is norethisterone. Norethisterone belongs to a group of medicines called progestogens which are female sex hormones. These medicines work by mimicking the effects of female sex hormones produced by the body.

Norethisterone Tablets are used to treat a number of disorders of the menstrual cycle including:

- pre-menstrual symptoms (such as headache, migraine, breast discomfort, water retention or changed behaviour before a period is due)
- abnormal, heavy or continuous bleeding from the uterus (womb) not related to a period
- heavy bleeding during a period
- painful periods
- endometriosis (a painful condition in which the type of tissue lining of the womb also occurs outside the womb)

Norethisterone Tablets are also used in advanced breast cancer and can be used to postpone a period.

2. BEFORE YOU TAKE NORETHISTERONE TABLETS

Do not take Norethisterone Tablets if you:

- have ever had a **reaction** to or been told that you are **allergic** to norethisterone or any of the other ingredients in the tablets

(see 'What Norethisterone Tablets contain' in section 6)

- are **pregnant** or suspect that you may be
- have **liver disease** or have/had a **tumour in the liver**
- have **abnormal bleeding from the vagina** of unknown cause
- have or have had **cancer of the breast or of the cervix, vagina, womb, ovaries or fallopian tubes**, unless you have been prescribed Norethisterone Tablets as part of the treatment for one of these conditions
- have or have had a high risk of **disease of your arteries**
- have **porphyria** (an inherited blood disorder)
- have had a **thrombosis** (a clot in a blood vessel in your leg or lungs)
- have had **jaundice** (yellowing of the skin and whites of the eyes), **severe itching or a rash due to Herpes virus during pregnancy**.

If any of the above statements apply to you, you should not take Norethisterone Tablets.

Norethisterone Tablets should not be taken by children or the elderly.

Speak to your doctor before taking Norethisterone Tablets if you:

- are **obese**
- have **liver problems**
- suffer from **depression**
- have **fits (epilepsy)**
- have **asthma**
- suffer from **migraine attacks**
- are suffering from **diabetes mellitus** or have to control the amount of sugar in your diet
- have **high blood pressure**
- have **heart or kidney disease**
- have any other condition which may be worsened by the **retention of fluid**
- are **immobile** or have recently had **surgery** or have been **involved in an accident** which reduces your mobility, as there is an increased risk of developing a blood clot in these situations
- are **due to have surgery** in future which might cause immobility, particularly surgery to your abdomen or lower limbs
- have anyone in your family who has had a **blood clot** in their legs or lungs.

If any of the above statements apply to you, you should speak to your doctor before taking Norethisterone Tablets.

Taking other medicines

Taking another medicine while you are taking Norethisterone Tablets can affect how it or the other medicine works. Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those you may have bought yourself without a prescription.

Please particularly check with your doctor if you are taking or need to take any of the following:

- the herbal remedy St John's Wort
- medicines taken for diabetes such as glibenclamide
- carbamazepine, oxcarbazepine, phenytoin, topiramate and barbiturates, used for epilepsy
- griseofulvin, an antifungal medicine
- rifamycins used to treat tuberculosis
- nevirapine used to treat viral infections
- ciclosporin, a medicine used after transplant surgery
- other female sex hormones such as the contraceptive pill or hormone replacement therapy (HRT).

If you have any doubts about whether you should take this medicine then talk to your doctor.

Pregnancy and breast-feeding

Norethisterone Tablets can affect the unborn child. You should not take Norethisterone Tablets if you are pregnant or wish to become pregnant.

If your period is late while you are taking these tablets, tell your doctor or pharmacist. You will need to have a pregnancy test before you start your next course of treatment.

Norethisterone passes into breast milk. You should not breast-feed whilst taking Norethisterone Tablets.

Driving and using machines

Norethisterone Tablets should not affect your ability to drive or use machines.

Important information for patients with an intolerance to some sugars

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. You should not take Norethisterone Tablets if you have certain types of intolerance.

3. HOW TO TAKE NORETHISTERONE TABLETS

Your doctor will decide the dose which is best for you. Always follow your doctor's instructions completely, and also follow any special instructions or warnings which appear on the label which the pharmacist has put on the package. If you do not understand, or are in any doubt, ask your doctor or pharmacist.

Unless instructed differently, take your tablets with a glass of water.

To treat pre-menstrual symptoms

For pre-menstrual symptoms the usual dose is two or three tablets a day from the 19th to the 26th day of your menstrual cycle (counting the first day of your period as day one). You may need to take treatment for several months.

To treat abnormal, heavy or continuous bleeding from the womb

For abnormal, heavy or continuous bleeding from the womb the usual dose is one tablet three times daily for ten days. Bleeding usually stops within one to three days. Once you have finished a course of Norethisterone Tablets, you will usually have a withdrawal bleed two to four days after taking the last tablet.

If there is no rise of morning temperature in the second half of the cycle, the abnormal bleeding may recur. To try and prevent this take one tablet twice daily from the 19th to the 26th day of your menstrual cycle (counting the first day of your period as day one).

To treat prolonged or heavy periods

For prolonged or heavy periods the usual dose is one tablet two or three times a day from the 19th to the 26th day of your menstrual cycle (counting the first day of your period as day one).

To relieve painful periods

For painful periods the usual dose is one tablet three times daily for 20 days, starting on day five of your menstrual cycle (counting the first day of your period as day one). Treatment will usually be needed for three or four cycles.

To treat endometriosis

For endometriosis (a painful condition in which the type of tissue lining of the womb also occurs outside the womb) the usual starting dose is two tablets a day beginning on day five of your menstrual cycle (counting the first day of your period as day one), and continuing for a number of weeks. If spotting occurs, the dose may be increased to a total of four or five tablets daily. When bleeding stops you may be able to go back to two to three tablets daily. Treatment is usually for four to six months continuously.

To postpone a period

To postpone a period (for example, in cases of too frequent bleeding, or special circumstances such as a forthcoming operation, travel, sport or a special occasion), the usual dose is one tablet three times daily, starting three days before the expected period, and continued until no further postponement is required. A normal period should occur two to three days after the last tablet.

To treat advanced breast cancer

For breast cancer, the usual starting dose is eight tablets daily, which may be increased to 12 tablets daily.

Once you have finished a course of norethisterone, you will usually have a menstrual bleed two to four days after taking the last tablet. If you do not have a period, you must make sure that you are not pregnant before taking any more tablets.

If you take more Norethisterone Tablets than you should:

If you take more Norethisterone Tablets than you should, contact your doctor, pharmacist or nearest hospital casualty department immediately. Take this leaflet and any remaining tablets with you.

If you miss a dose of Norethisterone Tablets

If you miss a dose of Norethisterone Tablets, take another dose as soon as you remember. Do not take a double dose to make up for a forgotten dose.

Stopping treatment with Norethisterone Tablets

You should continue to take Norethisterone Tablets for as long as your doctor tells you to. Do not stop taking this medicine without talking to your doctor first.

4. POSSIBLE SIDE EFFECTS

Like many medicines, Norethisterone may cause side effects in some patients, although not everybody gets them.

If you experience any of the following, you should contact your doctor immediately:

- swelling of the face and wheezing, which may be caused by a severe allergic reaction
- thrombosis (a blood clot in a leg or the lungs), particularly with high doses
- changes in liver function or jaundice (yellowing of skin and whites of eyes)
- migraine
- significant rise in blood pressure which may cause persistent headaches

You may need to stop your Norethisterone Tablets if any of the above side effects occur.

Other side effects include:

Reproductive

- breakthrough bleeding, particularly when treatment is continuous over a long period
- your periods may stop, or become irregular, prolonged or heavy
- spotting may be experienced
- breast changes, including breast discomfort
- ovarian cysts
- changes in sex drive
- pre-menstrual (pre-period) symptoms

Gut

- feeling sick or being sick
- stomach ache

Skin

- acne
- allergic skin rashes
- itching
- discoloration of the skin

General

- swelling due to fluid retention
- weight gain
- appetite changes
- headache
- dizziness
- depression
- drowsiness, tiredness
- sleeplessness
- high blood sugar
- fever

Eye

- worsening of vision in patients who are short sighted
- minor eye changes which may cause difficulties if you wear contact lenses

If you take Norethisterone Tablets for a long time

If you need to take the tablets for a long time, you may get breakthrough bleeding or an increase in body hair might occur.

If you suffer from migraine or epilepsy

If you suffer from migraine or epilepsy, you may find that your condition worsens

If you are due to have surgery to your abdomen or limbs

If you are due to have surgery in the future you may be asked to stop your Norethisterone Tablets four to six weeks beforehand to help prevent a thrombosis. 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 immediately.

5. HOW TO STORE NORETHISTERONE TABLETS

Norethisterone Tablets must be kept out of the reach and sight of children.

- Norethisterone Tablets should not be used after the expiry date stated on the carton. The expiry date refers to the last day of that month.
- The tablets should not be used if they show 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.

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.

6. FURTHER 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.

Marketing Authorisation Holder and Manufacturer

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

This leaflet was revised in June 2008.

104373/2
CP5
209952

 **WOCKHARDT**