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. 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 possible side effects not listed in this leaflet. See section 4.

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

What is this leaflet about?
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

What is Norethisterone?
• Norethisterone Tablets are a group of medicines called ‘progestogens’.
• Progestogens are similar to the natural female hormone progesterone.
• Norethisterone Tablets contain the active ingredient norethisterone.
• Norethisterone Tablets may be used in many different ways.

How Norethisterone Tablets work to treat or manage:
• Norethisterone Tablets are used for:

For premenstrual tension - if you are pregnant or not you are taking Norethisterone Tablets.

You will need to start taking Norethisterone Tablets for a few days after your next two periods. You will usually take 1 tablet 3 times a day (mg) for 10 days. A few days before you start your period you will usually have bleeding like a period. To stop your periods coming and to manage any particular problem.

You may have to stop taking Norethisterone Tablets for a few days after your next two periods. You will probably take 1 tablet a day for 5 days. You will need to start taking these tablets 3 days after your last period began.

Norethisterone Tablets can also interfere with some laboratory tests, so tell your doctor if you are taking 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 be pregnant, ask your doctor for advice before taking this medicine.

Norethisterone Tablets may be taken if you are pregnant as it is not a hormonal medicine. But it is not advisable to use an alternative method 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 that 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 machines has been seen with Norethisterone Tablets.

Norethisterone Tablets contain lactose. 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.

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

This recommended dose will depend on the condition you are being treated.

Norethisterone Tablets contain lactose. A type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking this medicine.

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.

This information can also be found on the label on the box the tablets come in. This information will help you understand what the usual dose is for a particular problem.

Norethisterone Tablets for heavy bleeding and other period problems
You will usually take 1 tablet 1 times a day (mg) for 10 mg. A few days before you start your period you will usually have bleeding like a period. To stop your periods coming and to manage any particular problem, your doctor may tell you to take Norethisterone Tablets for a few days after your next two periods. You will probably take 1 tablet a day for 5 days. You will need to start taking these tablets 3 days after your last period began.
Taking Norethisterone Tablets for endometriosis - You will usually take 1 tablet (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 (20-35 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 2 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 6 days of finishing the tablets.

If you do not have a period after you have finished a course of Norethisterone Tablets, check with your doctor to see if 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
If you forget to take a tablet 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 unusual severe, long-lasting 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 pain, tenderness or swelling in your calf, ankle or foot.
- You have purple discoloration 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 straight away 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), missed period, irregular bleeding, changes in discharge from the cervix, cervical erosions (this may be seen when you have a smear test), changes when you don’t ovulate (anovulation), breast pain and tenderness, a feeling of being trapped (intercourse, anxiety, inability to come off contraception).

Effects on the nervous system: headache, depression, dizziness, fatigue, difficulty sleeping, confusion, nervousness, a feeling of being trapped, anxiety, changes in appetite, abnormalities of the skin, taste changes, difficulty concentrating, loss of control of emotions.

Effects on the stomach and intestines: feeling or being sick, constipation, diarrhoea, dry mouth.

Effects on the liver: altered 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, increased decrease to some sugars like glucose, increased muscle breakdown (e.g. slow hand tremors, wasting, cramps muscle wasting), increase in size or fat on the adrenal glands (e.g. Cushingoid syndrome), cloudy vision, sugar in your urine.

Effects on your heart and circulation: blood clot, clotting disorders, clots in the veins due to blood loss due to clot, stroke, heart attacks, complications of heart failure, increased blood pressure, feeling your heartbeat, blood 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 facial hair, loss of hair, itching, sallow, hives.

Miscellaneous: fluid retention and swelling of hands and ankles, bloating, weight gain, raised temperature, changing in appetite, changes in sex drive, fatigue, iron deficiency anaemia.

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 Website: 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 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 (in tablets it 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 5 mg.

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, unscored tablets with “NE” on one side and a break line on the other.

Norethisterone Tablets are available in blister packs of 10, 72 or 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 2981/0125

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.

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