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

Norethisterone Tablets are a type of hormone used to treat various conditions. They are used to:

- Treat abnormal, heavy or continuous bleeding from the womb.
- Treat pre-menstrual symptoms.
- Replace hormones in hormone replacement therapy (HRT).

Before you take Norethisterone Tablets:

- You should not take Norethisterone Tablets if you are pregnant or wish to become pregnant. If you have any doubts about whether you should take this medicine talk to your doctor.
- You should not take Norethisterone Tablets can affect the unborn child. You should not take Norethisterone Tablets if you are pregnant or wish to become pregnant.
- If you are in a period when you are taking Norethisterone Tablets, tell your doctor or pharmacist. You will need to take a pregnancy test before you start your next course of treatment.

2. BEFORE YOU TAKE NORETHISTERONE TABLETS

Do not take Norethisterone Tablets if you:

- Have ever had a reaction to them.
- Are allergic to any ingredients in the tablets.

3. HOW TO TAKE NORETHISTERONE TABLETS

Follow the instructions on the label and any further instructions your doctor or pharmacist has given you. Take Norethisterone Tablets twice daily.

4. POSSIBLE SIDE EFFECTS

Side effects may include:

- Headache, migraine, breast discomfort, pre-menstrual symptoms.
- Water retention or changed behaviour.
- Itching or a rash due to Herpes virus.
- Jaundice.
- Abnormal bleeding.
- Depression.
- Severe abdominal pain.

5. FURTHER INFORMATION

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

- If you have further questions, please ask your doctor or pharmacist.
- 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.

- What Norethisterone Tablets contain. In section (ii) are pregnant or suspect that you may be
- Have you had any drug reactions to this medicine before? You should not take Norethisterone Tablets if you are pregnant or wish to become pregnant.

- If you are in a period when you are taking Norethisterone Tablets, tell your doctor or pharmacist. If you do not understand, or if you do have a high risk of disease of your arteries.
- The type of tissue lining of the womb also occurs outside the womb (endometriosis). The womb and Fallopian tubes may also become involved in an endometriosis.

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

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 when the pharmacist has put on the package. You should not breast-feed whilst taking Norethisterone Tablets.

- Do not use any special instructions or warnings which appear on the label when the pharmacist has put on the package.
- If you do not understand, or if you do have a high risk of disease of your arteries.

6. FURTHER INFORMATION

- The active ingredient in Norethisterone Tablets is norethisterone. Norethisterone belongs to a group of medicines called progestagens 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 conditions of the menstrual cycle.

- Menstrual disorders
- Endometriosis

Norethisterone Tablets are also used to treat abnormal breast cancer and can be used to put patients in remission. 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 particularly check with your doctor if you are pregnant or have recently taken any other medicines, even those you may have bought yourself without a prescription.

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

- Have a history of bowel disease.
- Have a family history of bowel disease.
- Have had immunosuppression.
- Have had a tumour in the liver

6. FURTHER INFORMATION

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

- Have any unusual bleeding.
- Have any other condition which may be worsened by the influence of blood clotting.
- Have a history of bowel disease.
- Have had surgery or have recently been in an accident which reduces your mobility.

- 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 speak to your doctor before taking Norethisterone Tablets.

Norethisterone Tablets are used to treat:

- Abnormal, heavy or continuous bleeding from the womb.
- Treatment for several months.
- Norethisterone Tablets can affect the unborn child. You should not take Norethisterone Tablets if you are pregnant or wish to become pregnant.

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

- Are mobile.
- Are developing a blood clot in these situations.

Further information

- What Norethisterone Tablets contain. In section (ii) are pregnant or suspect that you may be

- If you have had a history of bowel disease.
- If you have a blood clot in your leg or lung.
- If you 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 speak to your doctor before taking Norethisterone Tablets.

- Differences in dosage between the various types of contraception are not related to a period.

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

- 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 speak to your doctor before taking Norethisterone Tablets.

- Are developing a blood clot in these situations.

- Have a history of bowel disease.

- Have had jaundice, yellowing of the skin and whites of the eyes, severe itching or a rash due to Herpes virus during pregnancy.
To relieve painful periods
For painful periods, the usual dose is one tablet three times daily for 3 to 5 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 as a painful condition in which the tissue of 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 tablet of four to 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.

Norethisterone period
Norethisterone is prescribed for example, in cases of too frequent bleeding, or special circumstances such as a forthcoming operation, break 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 may be pregnant. Do not go on to another course of tablets until you are sure 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 have been prescribed, contact your doctor, pharmacist or nearest hospital casualty department immediately. Take this booklet 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 Tablets 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 breathing, which may be caused by a severe allergic reaction
• thrombosis (blot clots in a leg or the lungs), particularly with high dose
• changes in liver function (jaundice - yellowing of skin and whites of eyes)
• migraine
• sudden rise in blood pressure which may cause permanent 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 time
  • your periods may be late, and become irregular, prolonged or heavy
  • spotting may be experienced
  • breast changes, including breast discomfort
  • ovarian cyst
  • changes in sex drive
  • pre-menstrual period symptoms

• Gut
  • feeling sick or being sick
  • abdominal ache

• Skin
  • acne
  • allergic skin rash
  • discolouration of the skin

• General
  • swelling due to fluid retention
  • weight gain
  • appetite changes
  • headache
  • dizziness
  • depression
  • stomach ache
  • drowsiness, tiredness
  • weight gain
  • swelling due to fluid retention

• 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 breast hair or breast discomfort.

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 of children and of sight of children. A patient information leaflet should not be used after the expiry date stated on the container. The expiry date refers to the last day of that month.

The tablets should be kept in their original container, in order to protect from light.

Medicines should not be disposed of via waste water 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 white, round, 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
If you need to request a copy of this leaflet it is available in Braille, large print or audio please contact, free of charge:
0800 198 5000 (UK Only)

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