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

If you have any doubts about whether you should take the 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 need to become pregnant.

If your period is late while you are taking Norethisterone Tablets, tell your doctor or pharmacist. You will need to perform 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 allergy 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 when the pharmacist has put on the package. If you do not understand, or are in any doubt, ask your doctor or pharmacist.

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To relieve painful periods
For painful periods the usual dose is one tablet three times daily for 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 pain relief in painful conditions in which the lining of uterus grows in any of the organs, especially outside the uterus, 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 pain 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.

Norethisterone is not suitable for females who are pregnant or who breastfeed your baby.

4. POSSIBLE SIDE EFFECTS

You may need to stop taking 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 be late, heavy or irregular, prolonged or heavy.
  - Spontaneous abortion may occur.
- Digestive:
  - Cholestatic jaundice, i.e. a darkening of the skin and urine.
  - Liver damage.
  - Liver function tests abnormal.
  - Jaundice.
  - Yellowing of the skin and eyes.
  - Fever.
  - Sleeplessness.
  - Drowsiness, tiredness.
  - Depression.
  - Dizziness.
  - Weight gain.
  - Swelling due to fluid retention.
  - Stomach ache.
  - Feeling sick or being sick.
  - Depression.
- Skin:
  - Acne.
  - Stomatitis or mouth ulcers.
  - Non-specific skin rash.
  - Nervous:
  - Sleeplessness.
  - Headache.
  - High blood pressure.
  - Swelling of the face and lips.
  - General:
  - Jaundice.
  - Swelling of the limbs.
  - Previous allergic reactions to norethisterone.
  - Shortness of breath.
  - Wheezing.
  - Allergic skin reactions on the skin at sites of injection.
  - Swelling of the face and lips.
  - Swelling of the arms and legs.
  - Fever.
  - Rash.
  - Abnormal blood tests.
  - Itching.
  - Discoloration of the skin.

If you experience any of the following, you should contact your doctor immediately:
- Swelling of the face and limbs, which may be caused by a severe allergic reaction.
- Changes in body weight, which may be caused by fluid retention.
- Swelling in the lower abdomen.
- Nausea, vomiting, diarrhoea.
- Changes in liver function.
- Jaundice.
- Dizziness.

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 pain 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.

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

5. HOW TO STORE

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

6. FURTHER INFORMATION

What Norethisterone Tablets contain
The active substance is norethisterone.

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

Visit us on the internet:
Norethisterone Tablets are available online at our website.

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

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder: Menarini UK Ltd, Ash Road North, Wrexham, LL13 9RJ, UK.
Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9RJ, UK.

This leaflet was revised in June 2008.