

Norethisterone 5mg tablets

coding area

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

- 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 symptoms are the same as yours.

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1 What Norethisterone tablets are and what they are used for

Norethisterone tablets belong to a group of medicines called progestogens. These work by acting on receptors in the body to mimic or exaggerate the effects of the natural hormone, progesterone.

Norethisterone tablets may be used to treat:

- or prevent abnormal or unexpected bleeding from the uterus
- the symptoms of pre-menstrual syndrome which occur before a period including breast pain, headache, migraine, water retention and mood disturbances
- painful or heavy periods
- endometriosis
- certain types of breast cancer.

The tablets can also be used to stop periods.

2 Before you take

Do not take Norethisterone tablets and **tell** your doctor if you have:

- an **allergy** (hypersensitivity) to Norethisterone tablets or any of the other ingredients (see section 6)
- any **liver** disease or disturbance of liver function
- suffered from **jaundice** or **herpes during pregnancy**
- **Dubin-Johnson Syndrome** (chronic jaundice (yellowing of the skin or eyes)) or **Rotor Syndrome** (jaundice in childhood)
- **irregular vaginal bleeding** of unknown cause
- had a **blood clot** affecting the legs (deep vein thrombosis) or lungs (pulmonary embolism)
- had a recent **heart attack** (myocardial infarction) or suffer from **angina**

- an inherited disorder of the red blood pigment haemoglobin (**porphyria**)
- severe **itching**
- had **cancer** of the breast or genital tract (unless Norethisterone tablets are given as part of a cancer treatment programme).

Check with your doctor or pharmacist before taking Norethisterone tablets if you have:

- **not had a period** before starting a new course of norethisterone (it must be confirmed you are not pregnant)
- **diabetes**
- **epilepsy, migraine, asthma, kidney or heart** problems (norethisterone may cause fluid retention which can aggravate these conditions).

Taking other medicines

Please **tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- other hormonal products (oestrogens or progestogens)
- medicines used to treat epilepsy (e.g. phenobarbital, phenytoin, carbamazepine)
- medicines used to treat infections (e.g. rifampicin, nevirapine, tetracyclines, ampicillin, oxacillin, co-trimoxazole, ritonavir, nelfinavir)
- St John's Wort (hypericum perforatum-a herbal remedy)
- aminoglutethimide
- ciclosporin (to prevent transplant rejection)
- other medicines which can also cause fluid retention such as anti-inflammatory medicines (e.g. ibuprofen) or vasodilators.

Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant or are breast-feeding ask your doctor or pharmacist for advice before taking this medicine as **you should not take these tablets**.

Driving and using machines

Norethisterone tablets may make you feel dizzy, drowsy or affect your vision. Make sure you are not affected before you drive or operate machinery.

Sugar intolerance

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains a type of sugar called lactose.

Tests

If you go to a different doctor than the one who has prescribed you this medicine, or go to the hospital, let them know that you are taking Norethisterone tablets as they may affect certain tests.

3 How to take

Always take Norethisterone tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Swallow the tablets **with water**.

This medicine should be taken for as long as your doctor tells you to. If you finish the course of Norethisterone tablets you will usually have a menstrual bleed 2-3 days after the last tablet. If you do not have a period you must make sure you are not pregnant before taking more.

Day one of the cycle is the first day of your period.

Doses:

Adult

- **Abnormal bleeding** – 1 tablet three times a day for 10 days. Bleeding usually stops within 1-3 days. A period usually starts 2-4 days after stopping treatment.
- **Prevention of abnormal bleeding** – 1 tablet twice a day from the 19th - 26th day of the cycle.
- **Premenstrual Syndrome** - 2 to 3 tablets a day from the 19th - 26th day of the cycle. You will normally be treated for several months.
- **Stopping a period** - 1 tablet three times a day starting three days before the expected beginning of the period. Your period should occur 2-3 days after you have stopped taking the medicine.
- **Painful periods** - 1 tablet three times a day for 20 days starting on the 5th day of the cycle. You will usually be treated for 3-4 cycles.
- **Heavy periods** - 1 tablet two to three times a day from the 19th - 26th day of the cycle.
- **Endometriosis** - 2 tablets a day starting on the 5th day of your cycle. If you continue having small bleeds ("spotting"), the dosage may be increased to 4 to 5 tablets a day. Once bleeding has stopped the dosage may be reduced. You will usually be treated continuously for 4-6 months or longer.
- **Breast Cancer** - 8 tablets a day, the dosage may be increased to 12 tablets a day.

Elderly & Children - Not recommended.

If you take more than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include feeling or being sick, breast enlargement or vaginal bleeding.

If you forget to take the tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

If you stop taking the tablets

Talk to your doctor before you stop taking the tablets and follow their advice.

4 Possible side effects

Like all medicines, Norethisterone tablets can cause side effects, although not everybody gets them.

Stop taking Norethisterone tablets and contact your doctor immediately if you develop the following:

- a rise in blood pressure
- jaundice (yellowing of the skin or whites of the eyes)
- migraine type headaches.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- **Genital and urinary:** breakthrough bleeding, spotting, absence of bleeding, abnormal bleeding (irregular, increase or decrease), alterations of cervical secretions, cervical erosions, prolonged anovulation (not producing an egg), over production of breast milk, breast pain and tenderness
- **Gastrointestinal:** feeling or being sick
- **Heart:** blood clotting disorders (in the lower limbs, lungs or eye), inflammation of the veins
- **Liver:** changes in liver function
- **Nervous system:** depression, headache, dizziness, tiredness, difficulty in sleeping, nervousness, drowsiness, loss of concentration, vision disorders and intolerance to contact lenses
- **Metabolic and nutritional:** altered blood levels of cholesterol, changes in insulin and glucose control, diabetic cataract, worsening of diabetes mellitus, sugar in the urine
- **Skin:** acne, hair growth (especially on the top lip or chin), hair loss, rash which may be itchy, worsening of existing skin conditions

- **Hypersensitivity reactions:** severe allergic reaction including skin rash, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing
- **Other:** fluid retention, bloating, weight gain, fever, change in appetite, deepening of the voice, changes in the sex drive.

If you notice any side effects, they get worse, or if you notice any not listed, please tell your doctor or pharmacist.

5 How to store

Keep out of the reach and sight of children.

Do not store the tablets above 25°C and keep in the original packaging.

Do not use Norethisterone

tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

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 (the ingredient that makes the tablet work) is norethisterone. Each tablet contains 5mg of the active ingredient.
- The other ingredients are lactose, maize starch, magnesium stearate.

What Norethisterone tablets look like and contents of the pack

Norethisterone are white circular uncoated tablets.

Pack sizes are 30 tablets.

Marketing Authorisation Holder

Actavis, Barnstaple, EX32 8NS, UK

Manufacturer

CP Pharmaceuticals Ltd, Wrexham, LL13 9UF

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