

NORCOLUT TABLETS

Norethisterone (5 mg)

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What Norcolut is used for

Norcolut can be used for the treatment of menstruation cycle disturbances of different origin and for the treatment of premenstrual syndrome. It is also suitable for the prevention and suppression of lactation.

How Norcolut works

Norcolut works by imitating the effects of natural progesterone (female hormone).

Before you use Norcolut

- When you must not use it

Do not take this medicine if:

- you are allergic to norethisterone or any other ingredients of this medicine (listed in Product Description);
- you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis), your lungs (pulmonary embolus) or other organs;
- you know you have a disorder affecting your blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies;
- you need an operation or if you are off your feet for a long time;
- you have ever had a heart attack or temporary stroke symptoms;
- you have (or have ever had) a type of migraine called ‘migraine with aura’;
- you have any of the following diseases that may increase your risk of a clot in the arteries:
 - severe diabetes with blood vessel damage,
 - very high blood pressure,
 - a very high level of fat in the

blood (cholesterol or triglycerides),

- a condition known as hyperhomocysteinaemia;
- you have (had) an inflammation of the pancreas;
- you have liver disease or if you have ever had this and your liver function is still not normal;
- you have liver tumours or if you have ever had these;
- you have (or have ever had) sex-steroid influenced malignant tumour, or if you are suspected of having breast cancer or cancer of the genital organs.
- you have unexplained bleeding from your vagina;
- you are pregnant or if you think you might be pregnant;
- you are breast-feeding;
- if you have ever had jaundice or severe itchiness during pregnancy;
- you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir.

- Before you start use it

Before starting Norcolut treatment gynaecological check is necessary to exclude malignancy. Before you can begin taking Norcolut, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure and, depending upon your personal situation, may also carry out some other tests.

Pregnancy and lactation

Do not take Norcolut if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking Norcolut, stop taking it immediately and contact your doctor.

Do not take Norcolut if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Norcolut.

When should you contact your doctor?

Seek urgent medical attention

- if you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke (see “Blood clots” and “How to recognise a blood clot” sections below).

Take special care with Norcolut

- if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Products containing oestrogens may cause or worsen the symptoms of hereditary and acquired angioedema.
- if you have heart and vascular system disorders,
- if you have kidney diseases,
- if you have asthma,
- if you have epilepsy,
- if you have just given birth as you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking Norcolut,
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis),
- if you have varicose veins,
- if you have brown patches on your face or body (chloasma) or you are prone to them – if so avoid too much exposure to the sun or ultraviolet light (solarium, quartz-light therapy etc.),
- if you have hereditary or acquired angioedema,
- if any of the following diseases has ever occurred to you during pregnancy or while taking steroids because these diseases can worsen during Norcolut use:
 - a hearing problem (otosclerosis),
 - porphyria (metabolic disease with disorder of the formation of the pigment of the red blood cells),

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- gestational herpes (a blister-like rash that occurs during pregnancy),
- nervous system disorders (Sydenham's chorea - a problem with the nervous system causing jerky movements that you can't control),
- gallstones

How to recognise a blood clot

Seek urgent medical attention if you notice any of the following signs or symptoms:

Deep vein thrombosis:

- unusual unilateral leg pain and/or swelling

Pulmonary embolism:

- sudden breathlessness or rapid breathing
- sudden onset of coughing
- sharp chest pain which may increase with deep breathing
- severe light headedness or dizziness;
- rapid or irregular heartbeat;

Blood clot in the eye:

- sudden, partial or total loss of vision

Heart attack:

- chest discomfort, pressure, squeezing pain below the breastbone, sometimes radiating to the back, jaw, throat, arm and stomach
- rapid or irregular heartbeats
- anxiety, shortness of breath
- fullness, indigestion or choking feeling

Stroke:

- sudden weakness or numbness of the face, arm or leg, especially on one side of the body
- sudden confusion, trouble speaking or understanding
- loss of consciousness

Blood clots blocking other blood vessels:

- swelling and slight blue discolouration of an extremity
- severe pain in your stomach (acute abdomen)

Factors that increase your risk of a blood clot in blood vessels

- as you get older (particularly above about 35 years);
- smoking (women over 35 years should be strongly advised not to smoke if they wish to use a combined oral contraceptive (COC);
- obesity (body mass index (BMI) over 30 kg/m²);
- a positive family history (if one of your immediate family has had a stroke, heart attack or blood clot in the leg, lung or other organ at a young age);
- prolonged immobilisation, major surgery, any surgery on the legs, or major trauma;
- high blood pressure;
- migraine;
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides);
- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation);
- if you have diabetes.
- if you have liver function disturbances,
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease),
- if you have systemic lupus erythematosus (SLE –; a disease affecting your natural defence system),
- if you have haemolytic uraemic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys),

If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot may be increased even more.

Norcolut and tumours

In rare cases, benign liver tumours, and even more rarely, malignant liver tumours have been reported in users of hormonal substances. Liver tumours may lead to life-threatening bleeding in the stomach. Contact your doctor if you have unusually severe abdominal pain. The most important risk factor for cervical cancer is persistent HPV infection. The long-term use of sex

hormones may further contribute to this increased risk but there continues to be controversy about the extent to which this finding is attributable to confounding effects, e.g. sexual behaviour.

Breast cancer has been observed slightly more often in women using products containing sex hormones, but it is not known whether this is caused by the treatment. It is important to check your breasts regularly and you should contact your doctor if you feel any lump.

Psychiatric disorders

Some women using products containing sex hormones (such as hormonal contraceptives) have reported depression or depressed mood. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Lactose

Norcolut contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines can have an influence on the blood levels of Norcolut and can make it less effective, or can cause unexpected bleeding, such as medicines used for the treatment of:

- epilepsy (e.g. oxcarbazepine, carbamazepine, eslicabazepine, clobazam, perampanel, primidone, topiramate, rufinamid, felbamate, phenytoin and fosphenytoin)
- bacterial infections (e.g. rifampicin, rifabutin, rifamycin)
- virus infections (lopinavir, nevirapine, ribavirin, darunavir, efavirenz, fosamprenavir, nelfinavir, saquinavir, telaprevir)
- fungal infection (e.g. griseofulvin)

If you want to use herbal products containing St. John's wort (*Hypericum*

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perforatum) while you are already using Norcolut you should consult your doctor first.

The following medicines may impair the tolerability of Norcolut: atazanavir, cobicistat, boceprevir, tipranavir (used to treat certain virus infections).

Norcolut may influence the efficacy of other medicines, e.g.:

- ciclosporin (medicine used for the prevention of organ rejection following transplant surgery)
- lamotrigine (anti- seizures).
- warfarin, phenindione (medicine that prevents the clotting of blood)
- tranexamic acid (used to treat or prevent excessive blood loss),
- thalidomide, pomalidomide (used to treat a number of cancer)
- voriconazole (used to treat certain fungal infection)

Norcolut may diminish the therapeutic effect of antidiabetic medicines.

There are some antidiabetic, retinoid, antiemetic, antimalarial and anticancer medications which may reduce the effect of progestins (e.g. lixisenatide, exenatide, metreleptin, acitrecin, fosaprepitan, aprepitant, artemether, bexarotene, brigatinib, ixazomib).

How to use Norcolut

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- How much to use

Route of administration: oral.

The tablets are to be swallowed with some liquid.

The recommended dose is:

In premenstrual syndrome, mastodynia and irregular cycles: daily 5-10 mg (1-2 tablets) from the 16th to the 25th day of the cycle, possibly with oestrogen.

In dysfunctional uterine bleeding, cystic glandular hyperplasia of the endometrium (provided the functional nature of the bleeding was confirmed by a histological test within 6 months):

daily 5-10 mg (1-2 tablets) for 6-12 days. To prevent any relapse daily 5-10 mg (1-2 tablets) from the 16th to the 25th day of the cycle, in general combined with oestrogen.

Endometriosis, adenomyosis: daily 5 mg (1 tablet) from the 5th to the 25th day of the cycle for 6 months, or if taken continuously, it should be begun with 2.5 mg (half a tablet) daily on the 5th day of the cycle and to prevent inter-menstrual bleeding the dose should be increased by half a tablet every 2-3 weeks for as long as 4-6 months.

Postponement of menstruation: In cases of too frequent menstrual bleeding, and in special circumstances (e.g. operations, travel, sports) the postponement of menstruation is possible. Take 1 tablet of Norcolut three times daily for no longer than 10 to 14 days, starting 3 days before the expected onset of menstruation. A normal period should occur 2-3 days after the patient has stopped taking tablets.

To inhibit lactation (milk secretion)

- *if pregnancy was interrupted during weeks 16-28*, three tablets on day 1, two tablets daily on days 2 and 3, and one tablet daily on days 4 to 7 should be taken.
- *if pregnancy was interrupted during weeks 28-36*, three tablets on day 1, two tablets daily on days 2 to 7 should be taken.

For ab lactation (to suppress lactation): four tablets daily from the 1st to the 3rd day, three tablets daily from the 4th to the 7th day, and two tablets daily from the 8th to the 10th day should be taken.

In dysfunctional bleeding during the menopause: a daily dose of 5 mg (1 tablet) is recommended for 10-20 days in the second half of the cycle. It should be completed with oestradiol therapy.

- When to use it

Use as directed by your doctor or

pharmacist.

- How long to use it

Take the Norcolut for the duration as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it. Do not take double dose to replace the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause nausea, and withdrawal bleeding in females.

While you are using Norcolut

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking Norcolut.

Take Norcolut only with a doctor's prescription.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist. Do not give Norcolut to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine has no influence on the ability to drive and use machines.

Side effects

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

Possible side effects are:

- hypersensitivity (Contact a doctor

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immediately if you experience any of the following symptoms: swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also section “Warnings and precautions”));

- exacerbation of symptoms of hereditary and acquired angioedema;
- depression;
- dizziness;
- headache;
- migraine;
- visual disturbances;
- harmful blood clots in a blood vessel: in a leg or foot (deep vein thrombosis), in a lung (pulmonary embolism), mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack;
- abdominal pain;
- nausea;
- vomiting;
- jaundice (yellowing of the skin or eyes);
- acne;
- hair loss;
- chloasma (yellow brown patches on the skin);
- pain in extremity;
- absence of a menstrual period;
- painful periods;
- menstrual disorder;
- breakthrough bleeding;
- breast enlargement;
- breast tenderness/soreness;
- genital discharge;
- ovarian cyst;
- weight gain.

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.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine, even if you think the problems are not connected with the medicine.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Norcolut

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

Do not store any medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date which is stated on the pack after ‘EXP’. The expiry date refers to the last day of that month.

- Disposal

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.

Product Description

- What it looks like

White or almost white, flat, round, bevelled edge tablets with „NORCOLUT” engraving on one side and cross-scored for subdivision on the other.

- Ingredients

- Active ingredient
 - Norethisterone
- Inactive ingredients
 - potato starch
 - magnesium stearate
 - silica colloidal anhydrous
 - gelatine
 - talc
 - maize starch
 - lactose monohydrate.

- MAL number

MAL19871922AZ

Manufacturer

Gedeon Richter Plc.
H-1103 Budapest
Gyömrői út 19-21.
Hungary.

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.
Lot 5979, Jalan Teratai,
5 ½ Mile Off Jalan Meru,
41050 Klang, Selangor, Malaysia

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Visit your doctor or pharmacist immediately if you experience any side