

NORMENS[®] 5MG TABLET

Norethisterone Acetate BP equivalent to 5mg of Norethisterone

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Please read this leaflet carefully before you start using NORMENS[®]. It will advise you how it should be taken properly and when to tell your doctor about health-related conditions. If you have any questions or need more advice, ask your doctor, professional healthcare provider or pharmacist.

What NORMENS[®] is used for

NORMENS is used for timing of menstruation and to treat disturbances in monthly bleeding (dysfunctional bleeding), premenstrual complaints (premenstrual syndrome), endometriosis (a disease caused by unwanted womb-lining tissue growth outside the womb), prevention of lactation and complaints of breast pain (mastodynia).

How NORMENS[®] works

NORMENS contains norethisterone acetate, a progestogen, which is a synthetic hormonal product similar to the natural female hormone progesterone.

Before you use NORMENS[®]

Do not use NORMENS[®] if you have any of the following conditions listed below. If any of these apply to you, tell your doctor before starting to use NORMENS[®].

- When you must not use it

You should not use this medicine if:

- you are hypersensitive (allergic) to norethisterone or any of the other ingredients of NORMENS[®].
- you are pregnant or think you might be pregnant.

- you are breast-feeding.
- you have a disorder affecting the blood circulation (thromboembolic processes).
- you suffer or have suffered from a severe liver disease and you have been told by your doctor that your liver function values have not yet returned to normal. Symptoms of a liver disease may be, for instance, yellowing of the skin and/or itching of the whole body.
- you have or have had a benign or malignant liver tumour.

If any of these conditions appear for the first time while using NORMENS[®], stop taking it at once and consult your doctor.

- Before you start to use it

If any of the conditions listed below are present, appear for the first time, recur or worsen during treatment, close observation may be necessary so be sure to tell your doctor if any of these apply before starting NORMENS[®].

- you have diabetes, the requirement for oral anti-diabetics or insulin can change
- you have had a thrombosis/embolism
- you have liver disease
- you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet radiation
- you have a history of depression

Your doctor will discuss the benefits and risks of starting or continuing to use NORMENS[®] and determine if you should be closely supervised.

- Taking other medicines

Some medicines may stop NORMENS[®] from working properly. These include medicines that increase the metabolism of NORMENS[®] eg. enzyme inducers.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed,

including over-the counter medicines, and ask your doctor for advice before taking any other medicines.

How to use NORMENS[®]

- How much to use

The following dosages are recommended for the specific complaint; however, your doctor will prescribe the dose that is appropriate for your condition.

• **Dysfunctional bleeding**

1 tablet 3 times daily for 10 days. Usually bleeding stops within 1 to 3 days.

About 2 to 4 days after completion of the treatment, withdrawal bleeding will occur which is similar to the intensity and duration of normal menstruation.

If vaginal bleeding does not stop, although you have taken your tablets correctly, you should contact your doctor as another type of treatment and/or investigation may be necessary. This also applies when, after an initial cessation of bleeding, fairly heavy bleeding re-occurs during tablet-taking.

To prevent recurrence of dysfunctional bleeding, your doctor may decide that you should take NORMENS[®] each cycle 1 tablet 2 times daily from the 19th to the 26th day of the cycle. (The first day of the cycle = the first day of monthly bleeding). Withdrawal bleeding will occur a few days after the last tablet intake.

• **Premenstrual syndrome, breast tenderness**

Premenstrual symptoms such as headaches, depressive moods, water retention, and a feeling of discomfort in the breasts may be relieved by the administration of one tablet NORMENS[®] 2 to 3 times daily from the 19th to the 26th day of the menstrual cycle.

• **Timing of menstruation**

You should use this method only if you are not at risk of pregnancy during the treatment cycle.

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1 tablet NORMENS® 3 times daily for not longer than 10 to 14 days, beginning about 3 days before expected menstruation. A normal period should occur 2 to 3 days after medication has stopped.

• Endometriosis

Treatment should begin on the 5th day of the cycle with 1 tablet NORMENS® twice daily. If spotting occurs, the dose can be increased to 2 tablets twice daily. If bleeding ceases, dose reduction to the initial dose should be considered. Treatment continues for at least 4 to 6 months. With uninterrupted daily intake, ovulation and menstruation do not usually occur. After discontinuation of hormone treatment a withdrawal bleed will occur.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking NORMENS® for as long as your doctor recommends.

- If you forget to use it

The effect of NORMENS® could be reduced if you forget to take a tablet as directed. You should only take the last missed tablet, as soon as you remember, and then continue tablet intake at your usual time on the next day.

Do not take a double dose to make up for forgotten individual doses.

- If you use too much (Overdose)

If overdose is suspected, contact your local poison control center or emergency room immediately. Symptoms of overdose may include nausea, vomiting, breast enlargement and vaginal bleeding.

While you are using it

- Things you must do

Regular check-ups: When you are using NORMENS® your doctor will tell you to return for regular check-ups.

NORMENS® laboratory tests: If you need a blood test, tell your doctor or the laboratory staff that you are taking NORMENS because it can affect the results of some tests.

- Things you must not do

NORMENS® and breast feeding: You must not use NORMENS® if you are breast-feeding.

NORMENS® and pregnancy: You must not use NORMENS® if you are pregnant or think you might be pregnant.

- Things to be careful of

Taking NORMENS® : The tablets are to be swallowed whole with some liquid.

Contact your doctor as soon as possible if:

- you have severe headaches for the first time or it occurs often
- you have jaundice (yellowing of the skin or whites of eyes)
- you are going to use other medications (see also "*Taking other medicines*")
- you are to be immobilised or are to have surgery (consult your doctor at least six weeks in advance)
- you have unusual, heavy vaginal bleeding

You should also stop taking NORMENS® and see your doctor immediately if you notice:

- jaundice (yellowish skin, whites of the eyes)
- generalized severe itching
- that you are pregnant

Side effects

Like all medicines, NORMENS® can have side-effects, although not everybody gets them.

Tell your doctor if you notice any unwanted side effects, especially if severe or persistent, or if there is a change in your health that you think might be caused by NORMENS®.

Serious side-effects

Serious reactions associated with the use of NORMENS® are described in the section "Before you use NORMENS®". Please read this section carefully and consult your doctor where appropriate.

Other possible side-effects

During treatment for endometriosis, changes in bleeding pattern may occur including spotting, scanty bleeding and absence of bleeding.

Side-effects are more common during the first months of treatment with NORMENS® and disappear with continued treatment.

The following side-effects have been reported in users of NORMENS®, although NORMENS® could not always be confirmed as the cause. Listed below are possible side-effects by the parts of the body they affect:

Very common:

- Uterine/vaginal bleeding including spotting*
- Short periods, extremely light menstrual blood flow (hypomenorrhoea)*

Common:

- Headache
- Nausea
- Absence of periods (amenorrhoea)*
- Generalized swelling (oedema)

*In the treatment of endometriosis

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra-moh.gov.my (Consumers → Reporting Medicinal Problems/Side Effects/AEFI).

Storage and Disposal of NORMENS®

- Storage

Store at room temperature (below 30°C). Do not use after the expiry date stated on the package. Store all medicines properly and keep them out of reach of children.

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- Disposal

Medicines should not be disposed of via the wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

Product Description

- What it looks like?

White, round flat bevel edge, one side contains logo 'N' and other side is bisect.

- Ingredients

The active ingredient is:

Norethisterone Acetate BP equivalent to 5mg Norethisterone.

Inactive ingredients are:

Polyvinyl pyrrolidone (Povidone K-30),
Maize starch, Lactose monohydrate,
Magnesium stearate, Purified Talc,
Ethanol.

- MAL number:

MAL14075035AZ

Manufacturer

[®]Trade Mark



Renata Limited

Section VII,

Milk Vita Road, Mirpur,

Dhaka, Bangladesh

Product Registration Holder

VITAMODE SDN BHD

55 & 57, Lorong Sempadan 2,

(Off Boundary Road)

11400 Ayer Itam, Penang, Malaysia.

Date of Revision

13/06/2025

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