

Endosafe Tablets

Dienogest 2 mg

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What Endosafe is used for

Endosafe is a preparation for the treatment of endometriosis (painful symptoms due to displaced tissue of the lining of the womb).

Endosafe contains a hormone, the progestogen dienogest.

How Endosafe works

Dienogest is a nortestosterone derivative with no androgenic but rather an antiandrogenic activity of approximately one third of that of cyproterone acetate. Dienogest binds to the progesterone receptor of the human uterus with only 10% of the relative affinity of progesterone.

Despite its low affinity to the progesterone receptor, dienogest has a strong progestogenic effect in vivo.

Dienogest has no significant androgenic, mineralocorticoid or glucocorticoid activity in vivo. Dienogest acts on endometriosis by reducing the endogenous production of oestradiol and thereby suppresses the trophic effects of estradiol on both the eutopic and ectopic endometrium.

When given continuously, dienogest leads to a hypoestrogenic, hypergestagenic endocrine environment causing initial decidualization of endometrial tissue followed by atrophy of endometriotic lesions.

Before you use Endosafe

- When you must not use it

Do not take Endosafe if you:

- are allergic (hypersensitive) to dienogest or any other ingredients in this medicine
- have active venous thromboembolic disorder
- have arterial and cardiovascular disease, past or present (e.g. myocardial infarction, cerebrovascular accident, ischemic heart disease)
- have diabetes mellitus with vascular involvement
- have presence or history of severe hepatic disease as long as liver function values have not returned to normal
- have presence or history of liver tumours (benign or malignant)
- have known or suspected sex hormone-dependent malignancies
- have undiagnosed vaginal bleeding

If you think this may apply to you, do not use until you consulted your doctor.

Pregnant and Breastfeeding

There is limited information about the safety of Endosafe in pregnant women. Do not take Endosafe if you are pregnant, trying to get pregnant or think you may be pregnant without checking with your doctor.

It is not known whether the ingredients of Endosafe can pass into breast milk. Do not take Endosafe if you are breastfeeding without checking with your doctor.

- Before you start to use it

Talk to your doctor before taking Endosafe if you have or previously had any of the following conditions:

- diabetes
- migraine
- vaginal or uterine bleeding
- venous thromboembolic disorder
- heart disease
- liver disease or liver tumour
- blood pressure
- breast cancer
- ovarian cancer
- osteoporosis
- depression
- chloasma gravidarum

- Taking other medicines

Tell your doctor if you are taking or have recently taken any other medicines. This includes medicine you bought without a prescription.

How to use Endosafe

- How much to use

Always use Endosafe exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

- When to use it

Use as directed by your doctor.

- How long to use it

Continue taking Endosafe for as long as your doctor recommends.

- If you forget to use it

Endosafe will be less effective if you forgot to take a dose. If you missed one or more tablets, take one tablet only as soon as you remember, and then continue next day taking the tablet at your usual time.

If you vomit and/or have diarrhoea within 3-4 hours after taking Endosafe, there is a risk that the active substance in the tablet will not be taken up by your body. This situation is almost the same as forgetting a tablet. Therefore, you should take another tablet as soon as possible should this incident occur.

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

Consult your doctor or pharmacist on what you should do if you missed a 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 have taken too much of this medicine. Do this even if there are no signs of discomfort. You may need urgent medical attention.

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While you are using Endosafe

- Things you must do

- Take your medicine exactly as your doctor as told you
- Tell all the doctors, dentists and pharmacists treating you that you are taking Endosafe
- Tell your doctor immediately if you become pregnant while taking this medication

- 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
- Do not give Endosafe to anyone else, even if they have the same symptoms or condition as you

- Things to be careful of

Driving and using machines

No effect on the ability to drive or use machines has been seen with Endosafe.

Side effects

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

The followings have been observed during treatment with Endosafe:

- changes in bleeding pattern, such as spotting, irregular bleeding or amenorrhea
- headache
- breast discomfort
- depressed mood
- acne
- anaemia
- weight increase
- weight decrease
- increased appetite
- depression
- anxiety
- mood swings
- migraine
- dry eye
- tinnitus
- autonomic nervous system imbalance disturbance in attention
- unspecific circulatory system disorder palpitations
- palpitations
- hypotension

- dyspnoea
- nausea
- abdominal pain
- flatulence
- abdominal distension
- vomiting
- diarrhoea
- constipation
- abdominal discomfort
- gastrointestinal inflammation
- gingivitis
- acne alopecia
- dry skin
- hyperhidrosis
- pruritus
- hirsutism
- onychoclasia
- dandruff dermatitis
- abnormal hair growth
- photosensitivity reaction
- pigmentation disorder
- back pain
- bone pain
- muscle spasms pain in extremity
- heaviness in extremities
- urinary tract infection
- breast discomfort
- ovarian cyst
- hot flushes
- uterine / vaginal bleeding including spotting
- vaginal candidiasis
- vulvovaginal dryness
- genital discharge
- pelvic pain
- atrophic vulvovaginitis
- breast mass
- fibrocystic
- breast disease
- breast induration
- asthenic conditions irritability
- oedema

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.gov.my [Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Endosafe

Storage

Store below 30°C.

Store in the original package to protect from light and moisture.

Keep the medicine out of reach of children.

Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

White to off-white, round, flat faced beveled edge tablets debossed with “NC” on one side and “22” on other side.

- Ingredients

- Active ingredient:
Dienogest

- Inactive ingredients:

Lactose monohydrate (200M) & (30GR), Microcrystalline cellulose (PH101), Talc, Potato starch, Crospovidone Type A, Povidone (K-25), Purified water, Magnesium stearate

MAL number

MAL24116022ACZ

Manufacturer

Naari Pharma Private Limited
Manufacturing Block-1,
Plot No. 14-16 & 55-57,
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Nagar,
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Product Registration Holder

Lotus Healthcare Malaysia Sdn. Bhd.
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Date of Revision

15/11/2024

Serial Number

NPRA (R2) 23/238