

Evafact (Dienogest Tablets 2mg)

Dienogest Ph. Eur. 2mg

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What is Evafact used for

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

Evafact contains a hormone, the progestogen dienogest.

How Evafact 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 Evafact

-When you must not use it

Do not use Evafact:

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

If you think this may apply to you, do not use until you have checked with your doctor.

Pregnancy and lactation:

There is only limited information about the safety of Evafact in pregnant women. Do not take Evafact 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 Evafact can pass into breast milk. Do not take Evafact if you are breastfeeding without checking with your doctor. Ask your doctor or pharmacist for advice before taking any medicine.

-Before you start to use it

Talk to your doctor or pharmacist before taking Evafact tablets 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 medications

Tell your doctor or pharmacist if you're taking any other medicines, if you've taken any recently, or if you start taking new ones. This includes medicines you bought without a prescription.

How to use Evafact

-How much to use

Always use Evafact 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 or pharmacist.

-How long to use it

Continue taking Evafact for as long as your doctor recommends.

-If you forget to use it

Take the tablet as soon as you remember and carry on taking the tablets at the normal times. Consult your doctor or pharmacist on what you should do if you missed a dose.

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-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.

While you are using it

-Things you must do

Take your medicine exactly as your doctor has told you.

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

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 Evafact 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 Evafact.

Side effects

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

Tell your doctor/pharmacist/nurse immediately or as soon as possible and stop using Evafact if any of the following happens.

The following side effects have been observed during treatment with Evafact:

- Changes in bleeding pattern, such as spotting, irregular bleeding or amenorrhea
- Headache
- Breast discomfort
- Depressed mood
- Acne
- Anemia
- 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
- 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 reaction directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Evafact

-Storage

Store below 30°C. Store in the original packaging to protect from light.

-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 to off-white, round, flat faced bevelled edge tablets debossed with "NC" on one side and "22" on other side.

-Ingredients

- Active ingredient(s)
Dienogest

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- Inactive ingredient(s)
Lactose monohydrate
(200M & 30GR),
Microcrystalline cellulose
(PH 101), Potato starch,
Crospovidone, Povidone
(K25), Talc, Magnesium
stearate & Purified water

-MAL number

MAL24086029ACZ

Product Owner

Bharat Serums and Vaccines Limited
17th Floor, Hoechst House,
Nariman Point, Mumbai 400021,
Maharashtra, India

Manufacturer

Naari Pharma Private Limited
Manufacturing Block-1,
Plot No. 14-16 & 55-57, Sector-5,
IIE, Pantnagar, Rudrapur, Dist.
Udham Singh Nagar, Uttarakhand,
263153, India

Product Registration Holder

BSV Bioscience Malaysia Sdn. Bhd.
3, Jalan 19/1, 46300 Petaling Jaya,
Selangor, Malaysia.

Date of revision

13/11/2024

Serial Number

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