Novo Nordisk

Vagifem®

Each Vagifem® vaginal tablet contains:
25 µg estradiol (as hemihydrate).

The vaginal tablets are marked "NOVO 279".
Other ingredients: Lactose Monohydrate, Maize Starch, Magnesium Stearate, Methylhydroxypropylcellulose and Polyethylene Glycol 6000.

Each white Vagifem vaginal tablet comes in a single-use applicator. There are 15 applicators with vaginal tablets in each box.

Pharmaco-therapeutic group
Estrogen preparation (sex-hormone).

Manufacturer:
Novo Nordisk A/S
DK-2880 Bagsvaerd, Denmark

Indications
Vagifem is indicated for the local treatment of atrophic vaginitis due to estrogen deficiency.

Contraindications
* Known hypersensitivity to the components
* Active estrogen-dependant cancer
* Porphyria

Special warnings and special precautions for use

Warnings
Although the dose of 17ß-estradiol is low and the treatment local, systemic absorption may occur to a minor degree, especially during the initial 2 weeks.
The increased risk of endometrial cancer after systemic treatment with unopposed estrogens as well as concern about the possible risk of breast cancer during long-term use of systemical estrogen therapy should be kept in mind.
However, these risks depend on the dosage of estrogen and the duration of treatment.
Vagifem provides controlled release of a very low dose of 17ß-estradiol, and the possibility of stimulation of the endometrium and breast tissue is minimized.

Special precautions
Before initiation
Physical examination and a complete medical and family history should be taken prior to the initiation of any estrogen replacement therapy with special reference to blood pressure, examination of the breasts and the abdomen and a gynecological examination.
Women with an intact uterus with abnormal genital bleeding of unknown etiology or women with an intact uterus who have previously been treated with unopposed estrogens should be examined with special care in order to disclose a possible hyperstimulation/malignancy of the endometrium before initiation of treatment with Vagifem.

During therapy
As a general rule, estrogens should not be prescribed for longer than one year without another physical examination including a gynecological examination being performed.
If bleeding occurs during or shortly after therapy, diagnostic aspiration biopsy or curettage should be performed to rule out the possibility of uterine malignancy.

Interactions
Due to the low dose of estrogen as well as the fact that only marginal elevations of plasma 17 ß-estradiol have been observed, no interactions are expected to occur.

Pregnancy and lactation
Known or suspected pregnancy is a contraindication to Vagifem therapy.
Lactation is not relevant in women receiving Vagifem, however, estrogens are excreted in the milk of nursing mothers.

Effect on ability to drive and use machines
No effects known

Dosage and administration
Vagifem is administered deeply into the vagina, using the applicator.
* *Initial dose:* 1 vaginal tablet a day for two weeks.
* *Maintenance dose:* 1 vaginal tablet twice a week.
* Treatment may start on any convenient day.

Overdose
No effect of overdosing has been reported.
Vagifem is intended for local treatment intravaginally. The dose of 17ß-estradiol (25 µg) is so low that a considerable number of tablets would have to be ingested to approach the dose normally used for oral systemic treatment.
There is no specific antidote and treatment should be symptomatic.

Side effects
Few side effects such as slight vaginal bleeding, vaginal discharge, allergic reactions and skin rash have been reported.

Storage conditions
Store in a dry place, protected from light. Store below 25° C.
Do not refrigerate.
Keep out of reach of children.

Do not use this product after the expiration date marked on the carton.