

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

Vagifem® 10 µg vaginal tablets

Estradiol

Read all of this leaflet carefully before you start using Vagifem® 10 µg

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

Vagifem® 10 µg has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Vagifem® 10 µg is and what it is used for.
2. What you need to know before you use Vagifem® 10 µg.
3. How to use Vagifem® 10 µg.
4. Possible side effects.
5. How to store Vagifem® 10 µg.
6. Contents of the pack and other information.

1. What Vagifem® 10 µg is and what it is used for

Vagifem® 10 µg vaginal tablet is used to relieve menopausal symptoms in the vagina such as dryness or irritation. It is inserted into your vagina.

2. What you need to know before you use Vagifem® 10 µg

Do not use Vagifem® 10 µg if:

- You are allergic (hypersensitive) to estradiol or any of the other ingredients of Vagifem® 10 µg (see section 6);
- You have, have ever had, or you have a family history of breast cancer (mother, sister or grandmother);
- You have or have ever had, or think you might have a hormone dependent tumour, e.g. endometrial cancer (cancer of the lining of the womb);
- You have unusual vaginal bleeding which you have not told your doctor about;
- You have been told by your doctor that you have excessive growth of the lining of the womb (endometrial hyperplasia) and you are not being treated for it;
- You have or previously have had a blood clot inside the blood vessels of the legs or lungs (deep vein thrombosis or pulmonary embolism);
- If you have a blood clotting disorder (such as protein C, protein S or antithrombin deficiency).
- You have had a heart attack, stroke or have chest pain (angina);
- You have or have had a liver disease and your liver tests have not returned to normal;
- You have porphyria.
- You are pregnant;
- Do not use Vagifem® 10 µg if any of the above applies to you.

If you are not sure, talk to your doctor, pharmacist, nurse or other health care provider before using Vagifem® 10 µg.

Before you use Vagifem® 10 µg, tell your doctor if:

- You are known to have inherited genetic changes called BRCA1 and/or BRCA2 genes;
- You started your menstrual periods early (before the age of 12 years);
- You have a history of non-cancerous breast diseases, such as atypical hyperplasia or lobular carcinoma in situ;

- You had any previous treatment using radiation therapy to the chest or breast;
- You have been treated or exposed while in your mother's womb to a medicine called diethylstilbestrol (DES).

Warnings and precautions

Take special care with Vagifem® 10 µg

Check with your doctor before using Vagifem® 10 µg if you have or have ever had any of the conditions in the list below. Your doctor may want to follow you up more closely.

- Asthma;
- Epilepsy;
- Diabetes;
- Gallstones;
- High blood pressure;
- Migraines or severe headaches;
- Liver problems such as 'liver adenoma' (a benign tumour);
- Endometrial hyperplasia (thickening of the lining of your womb);
- Otosclerosis. This is when you lose your hearing over a period of time;
- Systemic lupus erythematosus (a disease affecting the skin, joints and kidneys);
- Blood clots or risk factors for blood clots (see "Section 4 Possible side effects");
- Leiomyoma (benign tumours of the womb) or endometriosis (growth of the womb lining outside the womb).

If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before using Vagifem® 10 µg.

Stop using Vagifem® 10 µg and consult a doctor straight away if you notice any of the following side effects:

- Yellow colouring of your skin or eyes (jaundice) or other liver problems;

- An increase in blood pressure;
- A migraine-type headache you have not had before;
- If you become pregnant.
- If you notice signs of a blood clot, such as painful swelling and redness of the legs;
 - sudden chest pain;
 - difficulty in breathing

If you develop any of the illnesses listed in “Section 2 What you need to know before you use Vagifem 10 µg: Do not use Vagifem® 10 µg.”

Medical check-ups

Before you start using Vagifem® 10 µg, your doctor will tell you about the risks and benefits of the treatment. Before you start using Vagifem® 10 µg and regularly during treatment, your doctor will check whether Vagifem® 10 µg is the right treatment for you. Your doctor will tell you how often to go for regular checkups, and will consider your general state of health. If you have a close relative (e.g. mother, sister, maternal or paternal grandmother), who has suffered from any serious illness such as blood clots or breast cancer, you might be at a higher risk for serious illness. Always tell your doctor about any close relative(s) suffering from serious illness.

As well as regular check-ups with your doctor, you should:

- Regularly examine your breasts for any changes, such as dimpling or sinking of the skin, changes in the nipple, or any lumps you can see or feel. Tell your doctor if you notice any changes.
- Go for regular breast screening and cervical smear tests.

Additionally, you are advised to join breast screening programs when offered to you. For mammogram screening, it is important that you inform the nurse/health care provider who is actually taking the x-ray that you use Vagifem®, as this medication may increase the density of your breasts which may affect the outcome of the mammogram. Where the density of the breast is increased, mammography may not detect all lumps.

Endometrial hyperplasia (excessive growth of the lining of the womb) and endometrial cancer (cancer of the lining of the womb)

Women who still have their womb and are taking systemic oestrogens have an increased risk of developing excessive growth of the lining of the womb (endometrial hyperplasia) and of developing endometrial cancer (cancer of the lining of the womb).

Breast cancer

Evidence suggests that using Vagifem® 10 µg does not increase the risk of breast cancer in women who had no breast cancer in the past. It is not known if Vagifem® 10 µg can be safely used in women who had breast cancer in the past.

Breast cancer has been diagnosed more often in women who use hormone replacement therapy than in women of the same age who do not use hormone replacement therapy. This increase in the number of breast cancer diagnoses gradually disappears during the course of the 10 years after stopping use of hormone replacement therapy. When you are using Vagifem® 10 µg, you must perform monthly breast self-examinations. Your doctor will advise you on when to report for breast examinations and any other appropriate investigations.

Stroke

There may be a higher risk of having a stroke if you are taking combined oestrogen-progestagen and oestrogen-only hormone replacement therapy (HRT). If you get migraine-type headaches, with or without disturbed or blurred vision, **stop using HRT and consult a doctor as soon as possible.**

Ovarian cancer

Use of systemic oestrogen alone and oestrogen plus progestogen therapies for at least 5 years have been associated with an increased risk of ovarian cancer in epidemiological studies.

Dementia

There is evidence for an increased risk of dementia in women older than 65 years, who were using systemic oestrogen/progestagen combination.

Gall bladder disease

Gall bladder disease has been reported after treatment with systemic oestrogen/progestagen.

Effects on the skin

Brown patches in the face (chloasma), skin rashes including red inflammation on the hands or the legs (erythema multiforme) or a bruise-like rash have been reported after treatment with HRT.

Other medicines with Vagifem® 10 µg

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, nurse or other health care provider for advice before taking Vagifem® 10 µg.

Do not use Vagifem® 10 µg if you are pregnant, or if you are breast-feeding.

If you get pregnant while you are using Vagifem® 10 µg, stop using it and consult a doctor straight away

Driving and using machines

No known effect.

3. How to use Vagifem® 10 µg

Do not share medicines prescribed for you with any other person.

Always use Vagifem® 10 µg exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Using this medicine

- You can start using Vagifem® 10 µg on any day which is best for you.
- Insert the vaginal tablet into your vagina with the applicator.

The 'USER INSTRUCTIONS' at the end of the leaflet tell you how to do this.

Read the instructions carefully before using Vagifem® 10 µg.

How much to use

- Use one vaginal tablet each day for the first 2 weeks.

Then use one vaginal tablet twice a week. Leave 3 or 4 days between each dose.

If you have the impression that the effect of Vagifem® 10 µg is too strong or too weak, tell your doctor or pharmacist.

If you use more Vagifem® 10 µg than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

If you forget to use Vagifem® 10 µg

If you forget a dose, use the medicine as soon as you remember.

Do not use a double dose to make up for a forgotten dose.

If you stop using Vagifem® 10 µg

Do not stop using Vagifem® 10 µg without talking to your doctor. Your doctor will explain the effects of stopping treatment. He or she will also discuss other possibilities for treatment with you.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Vagifem® 10 µg can have side effects.

Not all side effects reported for Vagifem® 10 µg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Vagifem® 10 µg, please consult your doctor, pharmacist, nurse or other health care provider for advice.

If any of the following happens, stop taking Vagifem® 10 µg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Vagifem® 10 µg. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

The following have been reported but the frequency is unknown:

- Aggravated migraine (severe headaches);
- Blood clot formation in a blood vessel (deep vein thrombosis);

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects include:

- Headache;
- Feeling sick (nausea) or vomiting;
- Stomach pain, swelling or discomfort;
- Indigestion (heartburn);
- Passing wind (flatulence);
- Vaginal bleeding, discharge or discomfort;
- An infection of the genitals caused by a fungus or inflamed vagina (itching, inflammation, discharge);
- Breast pain or tenderness;
- Swelling of your hands, arms, legs or feet

Less frequent side effects include:

- Anxiety;
- Body mass increased;
- Hot flush;
- High blood pressure.

The following have also been reported but the frequency is unknown:

- Breast cancer;
- Fluid retention;
- Diarrhoea;
- Application site reactions (including a vulvovaginal burning sensation), minor trauma caused by the intravaginal applicator.
- Changes in oestrogen levels when blood tests are done.

Side effects of HRT

The following side effects can occur with systemic oestrogen treatment:

- Myocardial infarction, congestive heart disease;
- Stroke;
- Gall bladder disease;
- Skin disorders including brown patches in the face, skin rashes including red inflammation on the hands or the legs (erythema multiforme), a bruise-like rash and itching;
- Risk of excessive growth of the lining of the womb (endometrial hyperplasia) and developing endometrial cancer (cancer of the lining of the womb) or an increase in size of fibroids (benign lumps) in the womb;
- Being unable to sleep (insomnia);
- Epilepsy;
- Loss of sex drive (libido);
- Deterioration of asthma;
- Loss of memory and other mental powers (dementia).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of Vagifem® 10 µg.

5. How to store Vagifem® 10 µg

Store at or below 25 °C. Do not refrigerate.

Keep the blisters in the outer carton until required for use.

Store all medicines out of reach of children.

Do not use Vagifem® 10 µg after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets). The used applicator may be disposed together with household waste.

6. Contents of the pack and other information

What Vagifem® 10 µg contains

The active substance is estradiol 10 micrograms (as estradiol hemihydrate), a female sex hormone.

The other ingredients are: hypromellose, lactose monohydrate, macrogol 6000, maize starch and magnesium stearate.

What Vagifem® 10 µg looks like and contents of the pack

A white, film-coated, biconvex tablet, engraved with NOVO 278. Diameter 6 mm.

Each film-coated vaginal tablet is contained in a disposable single-use polyethylene/polypropylene applicator.

The applicators are packed in transparent PVC/aluminium foil blisters.

8 packs outer carton contain 2 blister cards of 4 applicators with inset tablets.

18 packs outer carton contain 3 blister cards of 6 applicators with inset tablets.

24 packs outer carton contain 4 blister cards of 6 applicators with inset tablets.

Holder of certificate of registration

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This leaflet was last revised in

03 December 2024.

Registration number

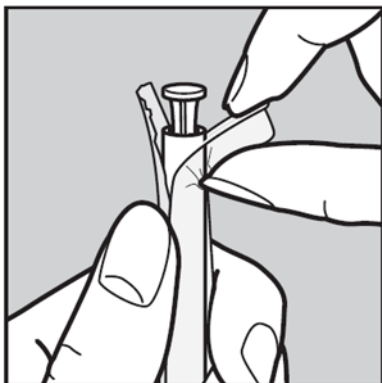
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USER INSTRUCTIONS

How to use Vagifem® 10 µg

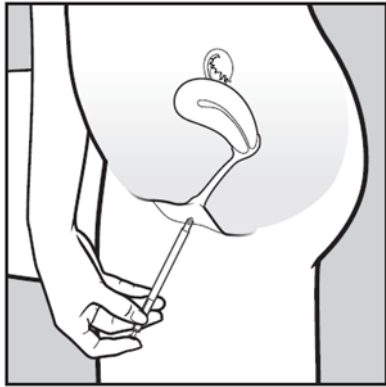
1. Tear off one single blister pack.

Open the end as shown in the picture.



2. Insert the applicator carefully into the vagina.

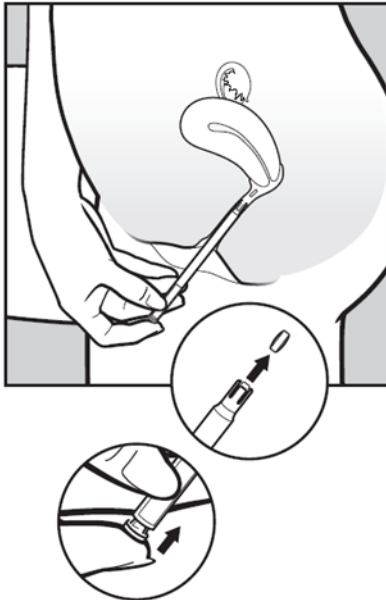
Stop when you can feel some resistance (8-10 cm).



3. To release the tablet, gently press the push button until you feel a click.

The tablet will stick to the wall of the vagina straight away.

It will not fall out if you stand up or walk.



4. Take out the applicator and throw it away together with household waste.

