



What do I need to know about Vagirux[®]?

(estradiol hemihydrate 10 microgram) vaginal tablets

Welcome!

About this guide

You have been given this guide as you were prescribed Vagirux for the treatment of vaginal atrophy due to reduction in oestrogen levels following the menopause.

It contains information about how Vagirux works and what you should expect from treatment.

Disclaimer

Please carefully read the leaflet that comes in the Vagirux pack in addition to this patient leaflet.



Please visit www.myvagirux.co.uk for more information, including a video demonstration explaining how to use Vagirux.
Password for website: **Vagirux01**



GEDEON RICHTER

Our ambition is to help women achieve theirs

What is the menopause?

The menopause is a time when women stop having periods, and experience fluctuating levels of the hormone estradiol.

It is a natural part of ageing that usually occurs between 45 and 55 years of age, when the ovaries stop producing the female hormones oestrogen and progesterone, and no longer release an egg each month.

The average age of menopause in the UK is 51 years, although for some women it can occur earlier or later in life. The drop in hormone levels during the menopause is associated with a number of symptoms, with hot flushes being one of the most common.

Almost two thirds of women of menopausal age in the UK are affected by symptoms of menopause.



Oestrogen deficiency results in a wide range of symptoms



Vasomotor:

Hot flushes, night sweats
(can lead to sleep disturbances)



Urogenital:

Vaginal atrophy leading to vaginal dryness, vaginal irritation, dyspareunia, urinary tract infections



Psychological:

Low mood, minor anxiety, mood changes, irritability, memory and concentration loss



Musculoskeletal:

Joint and muscle aches, bone loss, leading to osteoporosis and risk of fragility fractures



Other signs and symptoms:

Headaches, fatigue, palpitations, lack of interest in sex

What is vaginal atrophy?

Vaginal atrophy is a thinning and drying of the vaginal walls as a result of the natural drop in the levels of oestrogen in your body after the menopause.

Common symptoms include vaginal dryness and irritation, dyspareunia (recurring pain during sexual intercourse) and increased urination frequency, urgency, incontinence, or burning.

Up to 50% of postmenopausal women have at least some degree of vaginal atrophy.

Vaginal atrophy most often happens in late post-menopause. In more severe cases, women may have discomfort sitting, exercising, or wearing tight-fitting clothing.

Ideally you should start treatment for vaginal atrophy as early as possible and continue it to maintain the benefits.



What is hormone replacement therapy (HRT)?

HRT is a treatment that replaces the hormones in your body that decline over the course of the menopause.

There are many types of HRT, varying in the hormones they replace, the ways they are taken, and the treatment schedules they follow.

Most women take a combination of oestrogen and progestogen. In most circumstances, women who have had their womb removed can take oestrogen on its own.

Ways of taking HRT include sprays, vaginal or oral tablets, patches, gels, vaginal creams, pessaries, and rings.

What is Vagirux?



An HRT to relieve menopausal symptoms in the vagina such as dryness or irritation, also known as vaginal atrophy. Vagirux is not for treating non-vaginal symptoms (such as hot flushes).



Replaces oestrogen normally produced in the ovaries of women with estradiol (estradiol is exactly the same as the hormone oestrogen).



Administered by vaginal tablet, so the hormone is only released where it is needed.



Use one tablet every day for two weeks, then one tablet twice a week.



Vagirux is supplied as 24 tablets with a reusable applicator. This aims to reduce the amount of plastic waste contributed by Vagirux, versus other products with single-use applicators. The Vagirux applicator can be recycled.

How does Vagirux work?

Vagirux is inserted as a tablet into your vagina, so the hormone is released locally, where it is needed.

The tablets adhere to the vaginal wall and release the oestrogen in a controlled way through the hydrated gel layer it forms. This replacement oestrogen can reduce irritation by keeping the vagina moist, elastic, and acidic.

Vagirux works locally, as it is inserted directly into your vagina. This means that Vagirux has a lower risk of side-effects compared with other systemic HRT treatments that work throughout the body (e.g. those taken orally or as patches, gels or spray).

Vagirux inserter
14cm (5½") actual size



Good to know



Dosage

One vaginal tablet every day for two weeks, then one tablet twice a week (leave three or four days between doses). If you miss a dose, take it as soon as you remember; you should avoid a double dose.



Stopping use

In most cases don't stop using Vagirus without talking to your doctor. They will be able to explain the effects of stopping treatment and discuss your options with you.

However, if you experience any of the following you should stop taking Vagirus immediately and speak with your doctor:

- Jaundice or deterioration in liver function
- Significant increase in blood pressure
- New onset of migraine-type headache
- Pregnancy



Medical history

Before you start (or restart) HRT, your doctor will ask about your and your family's medical history and may perform a physical examination, including an examination of your breasts and/or an internal examination.



Check-ups

Once you have started on Vagirus you should see your doctor for a check-up at least once a year.



Pregnancy

Vagirus isn't a contraceptive. If it is less than 12 months since your last menstrual period or you are under 50 years old, you may still need to use additional contraception to prevent pregnancy. Speak to your doctor for advice.

Do not use Vagirus if...

If you have experienced any of the following conditions, or are unsure of whether they apply to you, talk to your doctor before using Vagirus:

- You are allergic (hypersensitive) to estradiol or any of the other ingredients of Vagirus
- You have or have ever had breast cancer, or you are suspected of having it
- You have or have ever had cancer which is sensitive to oestrogens, such as cancer of the womb lining (endometrium), or you are suspected of having it
- You have any unexplained vaginal bleeding
- You have excessive thickening of the womb lining (endometrial hyperplasia) that is not being treated
- You have or have ever had a blood clot in a vein (thrombosis), such as in the legs (deep venous thrombosis) or the lungs (pulmonary embolism)
- You have a blood clotting disorder (such as protein C, protein S or antithrombin deficiency)
- You have or have recently had a disease caused by blood clots in the arteries, such as a heart attack, stroke or angina
- You have or have ever had a liver disease and your liver function tests have not returned to normal
- You have a rare blood problem called 'porphyria', which is passed down in families (inherited)

If any of the above conditions appear for the first time while using Vagirus, stop using it at once and consult your doctor immediately.

What you should be aware of

The use of HRT carries risks, which need to be considered when deciding whether to start or carry on using it.

You should let your doctor know if you have or have ever had any of the following problems, before you start the treatment, as these could return or worsen during treatment:

- Asthma
- Epilepsy
- Diabetes
- Gallstones
- High blood pressure
- Migraines or severe headaches
- A liver disorder, such as a benign liver tumour
- Growth of womb lining outside your womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia)
- A disease affecting the eardrum and hearing (otosclerosis)
- A disease of the immune system that affects many organs of the body (systemic lupus erythematosus; SLE)
- Increased risk of getting an oestrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer)
- Increased risk of developing blood clots (thrombosis)
- Fibroids inside your womb
- A very high level of fat in your blood (triglycerides)
- Fluid retention due to cardiac or kidney problems
- Hereditary and/or acquired angioedema

The following risks apply to HRT that is taken systemically and circulated in the blood, like patches, gels, sprays, or an oral tablet. Because Vagirux is administered locally in the vagina, circulation in the blood is very low. It is less likely that the conditions mentioned below will get worse or come back during treatment with Vagirux, but you should see your doctor if you are concerned:

- Breast cancer
- Ovarian cancer (varies with age)
- Blood clots in a vein (thrombosis)
- Heart disease
- Stroke
- Memory loss



It's worth noting HRT will not prevent memory loss. There is some evidence of a higher risk of memory loss in women who start using HRT after the age of 65. Always speak to your doctor for advice.



Blood clots are more likely if you're older and: you are unable to walk for a long time because of major surgery, injury or illness; are seriously overweight; have any blood clotting problem that needs long-term treatment; have close relatives who have had a blood clot; have systemic lupus erythematosus (SLE); have cancer.

When to stop using Vagirux

You should stop using Vagirux immediately if you develop any of the conditions outlined in “Do not use Vagirux if...”

In addition, stop using Vagirux if you have or develop any symptoms of:

- Yellowing of your skin or the whites of your eyes (jaundice). These may be signs of liver disease
- Significant increase in blood pressure (symptoms may include headache, tiredness, dizziness)
- New migraine-like headaches
- Pregnancy

Possible side effects

Common

Headaches, stomach pains and vaginal bleeding, discharge, or discomfort

Uncommon

Fungal infection, nausea, rash, weight increase, hot flush, hypertension

Very rare

Diarrhoea, fluid retention, migraines, generalised hypersensitivity (e.g. anaphylactic reaction/shock)

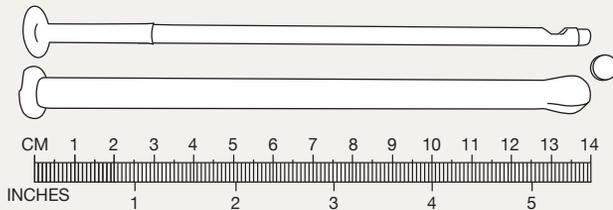


If you get any side effects (even ones not listed in this leaflet), talk to your doctor. You can also report side effects directly at <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store.



How to take Vagirux

- You can start on any convenient day
- Tablets are packed in blister packs
- Use the applicator to insert the tablet into your vagina
- Any vaginal infections should be treated before you start Vagirux therapy
- Applicators can be used up to 24 times and should be cleaned after every use, following the simple cleaning instructions on the next page

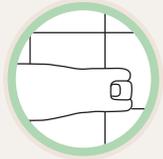


The applicator device consists of a plunger and an outer tube component. These can be pulled completely apart for cleaning. The vaginal tablets are provided in a separate blister pack within your Vagirux box.

Step-by-step instructions for use

To load the applicator with a tablet for the first use of Vagirux:

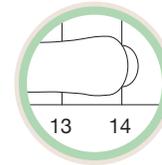
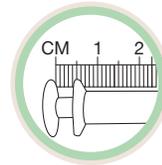
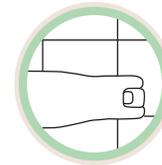
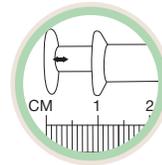
1. Remove the applicator device from its sealing plastic foil. Open the end as shown in the picture.
2. While holding the tube, gently pull the plunger out of the back of the applicator's outer tube until you hear one click. Keep pulling gently until it comes to a stop. You should not pull the plunger past a second click. *If this happens, please follow the instructions on the next page regarding reloading the applicator after washing.*
3. Take a vaginal tablet from the separate blister pack and place it firmly in the holder of the applicator's end (the wide end). The applicator's wide end has small 'teeth' that hold the tablet in place. The vaginal tablet should be pushed into the applicator device until it is **fully inside**, and the 'teeth' are holding the tablet securely. If the tablet is not fully inserted into the applicator, it will not be held securely and may fall out during administration.
4. Insert the applicator carefully into the vagina. Stop when you can feel some resistance (normally once it is about 8–10 cm (3¼–4") into the vagina).
5. Release the vaginal tablet by gently pushing the end of the plunger past the second 'click' until it stops and the plunger meets the end of the applicator tube. This releases the tablet. The tablet will stick to the wall of the vagina straight away. It will not fall out if you stand up or walk.



To clean and re-load the applicator after the first use:

1. After use, the applicator should be pulled apart into its constituent elements (tube and plunger), and cleaned according to the following procedure:
 - Withdraw the plunger from the applicator
 - Clean both parts (tube and plunger) with mild soap and rinse with warm tap water for 5 seconds. Rinse the tube's inner and outer surface
 - If necessary, remove large amounts of remaining water from both parts (tube and plunger) by shaking off the water
 - Air-dry both the tube and the plunger on a clean surface (e.g. paper towel)
 - Reintroduce the plunger into the applicator tube for subsequent uses
2. To reload the applicator after cleaning, the plunger should be pushed into the outer tube until one click is heard (not two clicks). The plunger is now in the correct position to insert a new vaginal tablet. In the correct position, the gap between the end of the plunger and the end of the outer tube is approximately 10mm (1cm / ½"). If the gap between the end of the plunger and the bottom of the outer tube is less than this, the tablet cannot be fully inserted into the applicator. The vaginal tablet will not be held securely in the applicator and may fall out during administration.

3. The vaginal tablet should be pushed into the wide end of the applicator device until it is **fully inside**, and the 'teeth' are holding the tablet securely.



4. Insert the applicator carefully into the vagina. Stop when you can feel some resistance (normally once it is about 8–10 cm (3¼-4") into the vagina).
5. Release the vaginal tablet by gently pushing the end of the plunger past the second 'click' until it stops and the plunger meets the end of the applicator tube. This releases the tablet. The tablet will stick to the wall of the vagina straight away. It will not fall out if you stand up or walk.



Disposing of the Vagirux applicator:

- After the applicator has been used up to 24 times, you should throw it away in the household waste or recycle it. A new applicator should be used with every new pack of Vagirux.

FAQs

What if Vagirux doesn't work for me?

Speak to your doctor if you are still being troubled by vaginal symptoms of menopause. They will aim to prescribe the lowest dose for as short a time as necessary to treat your symptoms but can increase the dose of other systemic HRTs according to your individual needs.

If your symptoms remain unchanged, speak with your doctor.

What happens if I'm switching to Vagirux from another treatment? Will the dose be strong enough?

There is only one dose for Vagirux. Speak to your doctor if you are still being troubled by vaginal symptoms of menopause.

How long can I use Vagirux for?

Speak with your doctor about your symptoms and frequency of risk assessments. Vagirux should be taken only for as long as it relieves the symptoms of the menopause that impact on your life – this should be regularly assessed by your doctor. They will discuss your symptoms with you at your check-ups, as well as the benefits and risks of continuing treatment.

What should I do if I've used more Vagirux than I should?

If you have used more Vagirux than you should, talk to a doctor or pharmacist.

Can I continue to use Vagirux if I'm going to have surgery?

If you are going to have surgery, tell the surgeon that you are using Vagirux. If you are likely to be immobile for a long time after elective surgery, you may need to stop using Vagirux about 4 to 6 weeks before the operation to reduce the risk of a blood clot. Ask your doctor when you can start using Vagirux again. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Can I use Vagirux with other systemic HRT products, like patches, gels, sprays or an oral tablet?

You can use Vagirux with other systemic HRT products, however only if advised to do so by your doctor. When stopping treatment with systemic HRT products, some doctors may advise using a local HRT like Vagirux, which is inserted directly into your vagina.

Is it important to clean my applicator?

It's important to only use a clean applicator. Clean the applicator after each use, and only use up to 24 times.

How do I store Vagirux?

Keep Vagirux out of the sight and reach of children and in a cool, dry place. Vagirux does not require any special storage conditions.

How do I dispose of the Vagirux applicator once it has been used 24 times or if I decide to stop treatment?

You can dispose of the applicator in your household waste or local plastic recycling, if available.

What if I have other questions about Vagirux?

If you still have questions about Vagirux, refer to the leaflet that comes in the Vagirux pack or speak with your doctor.



GEDEON RICHTER

Our ambition is to help women achieve theirs

Gedeon Richter have been working in women's healthcare since 1901. Women's healthcare, as well as their psychological and social wellbeing, are the driving force behind every innovation.

If you experience any side effects, including ones that are not listed in this booklet or the patient information leaflet, speak to your doctor, pharmacist, or nurse.

Reporting side effects helps us provide more information about the safety of Vagirux®.

You can report them directly at:

<https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store.

Please visit www.myvagirux.co.uk or use the QR code below for more information, including a video demonstration explaining how to use Vagirux. Password for website: **Vagirux01**



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