

Lenzetto®

WHAT DO I NEED TO KNOW ABOUT LENZETTO®?

(estradiol)



GEDEON RICHTER

WELCOME!

WHY HAVE I BEEN GIVEN THIS GUIDE?

You have been given this guide as you have been prescribed Lenzetto for symptoms of menopause, which result from a decline in your own oestrogen levels.

This guide contains information on how Lenzetto works and what you should expect from treatment.

This guide does not replace the leaflet that comes in the Lenzetto pack, which should be read along with this guide.



WHAT IS LENZETTO?



A hormone replacement therapy (HRT) for the relief of symptoms occurring after menopause, such as hot flushes



For postmenopausal women with at least six months since their last natural period



Administered as a spray solution which contains small amounts of a medicine called estradiol



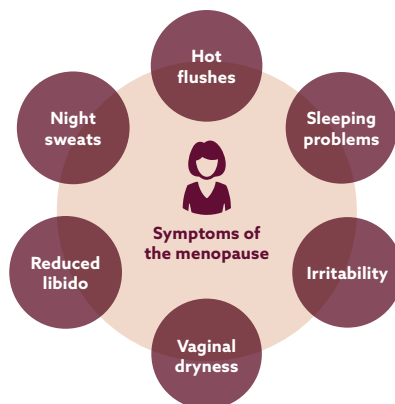
Used every day in the same position(s) - with the number of sprays depending on the severity of your symptoms and doctor's instructions

WHAT IS THE MENOPAUSE?

The menopause is a time where women stop having periods, and experience fluctuating levels of the hormone oestradiol. It is a natural part of aging 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. However, for some women it can occur earlier or later in life, and if a woman has her ovaries removed surgically it will occur immediately.

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.



WHAT IS HRT?

Hormone replacement therapy (HRT) is a treatment that replaces the hormones in your body which decline over the course of the menopause. There are many different types of HRT, varying in the hormones they replace, the ways they are taken, and the treatment plans they are given by.

HORMONES

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

These include sprays, tablets, patches, gels, vaginal creams, pessaries, and rings.

TREATMENT PLANS

HRT may be taken without stopping, or used in cycles where you take oestrogen without stopping but only take progestogen every few weeks.

HOW DOES LENZETTO WORK?

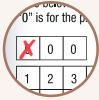


Lenzetto is a HRT treatment that replaces the hormone oestrogen in women who are experiencing symptoms associated with oestrogen deficiency after the menopause.

Lenzetto is a spray solution which contains a hormone called estradiol, which is a natural oestrogen. When sprayed onto the skin as directed, it passes through the skin into your bloodstream where it travels throughout the body to alleviate symptoms.

Because it passes straight from the skin into the bloodstream, Lenzetto bypasses the liver. This is different from HRT treatments that are taken as tablets.

WHAT DO I NEED TO KNOW ABOUT USING LENZETTO?



Do not dispose of your Lenzetto carton as you will need this to track your treatment



Before using a new Lenzetto device for the first time, you must prepare (or prime) the applicator. The patient information leaflet includes step-by-step preparation/priming instructions



Do not tilt the Lenzetto device. It should be held in the upright position when sprayed



Lenzetto should be sprayed in the same position(s) along the inner forearm each day*



Do not rub Lenzetto in after being sprayed



Lenzetto dries in around 2 minutes. Wait until the spray has dried before getting dressed



You can wash the area where you sprayed Lenzetto one hour after application



Avoid skin-to-skin contact until one hour after application



When using sunscreen, avoid the part of the skin where Lenzetto will be applied for at least one hour before or after application



One spray (containing 90 microliters of Lenzetto) is the recommended starting dose. If your menopause symptoms persist after four weeks of continuous treatment, you should see your doctor to discuss how your symptoms are being managed. It could be that the dose is not high enough, and your doctor may increase your dose to two or three sprays per day



If you are having blood tests taken as part of your menopause management, let your clinician know which arm your Lenzetto is routinely applied to. They will then take blood samples from the alternative arm

Lenzetto contains alcohol

This medicine contains 65.47 mg of alcohol (ethanol) in each dose which is equivalent to 72.74%w/v. It may cause burning sensation on damaged skin.

Alcohol-based liquids are flammable. Keep away from fire. Avoid open flame, lit cigarette, or some hot devices (e.g. hairdryers) while applying the spray to your skin, until the spray has dried.

* If you have difficulty applying to the inner forearm, Lenzetto may also be applied to the inner thigh.

HOW DO I TAKE LENZETTO?

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

Lenzetto is applied as a spray directly to your skin, with the dose corresponding to the number of sprays you apply per day.

Dose adjustment

Your doctor will prescribe the lowest effective dose for the shortest duration of time necessary to treat your symptoms.

- During the treatment your doctor may adjust the number of sprays you need to apply according to the severity of your symptoms.
- Be sure to let them know if your symptoms do not improve, this could be because your current dose is not strong enough.

Combination treatment

If you have not had a hysterectomy, your doctor will give you another hormone called progestogen to offset the effects of oestrogens on the lining of the womb, preventing it from becoming too thick.

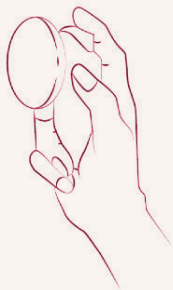
If you are prescribed tablets, they will explain to you how to take these tablets and outline any effects they may have on you. If you have had a hysterectomy, but have a history of endometriosis, your doctor may consider adding a progestogen to your oestrogen HRT treatment.

If you already have a progestogen-containing IUS in your womb, tablets may not be needed.



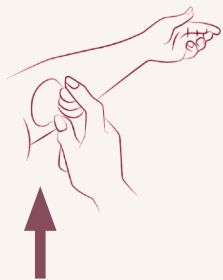
APPLICATION STEP-BY-STEP

1 Preparing (priming) the applicator



- A. Before spraying the first dose from a new device, it should be prepared for use by spraying three times with the cover on
- B. The device should be held upright as shown. With the cover on, press the button right down three times with your thumb or index finger
- C. The medicine is now ready to use
- D. The device only needs to be prepared the first time you use it – you don't repeat this process for each dose

2 Applying your daily dose



Hold upright

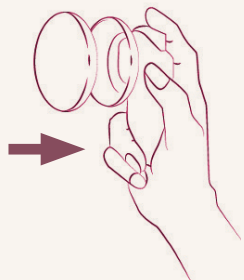
- A. Lenzetto should not be used on broken or damaged skin. The spray should be applied to the inner forearm. Do not apply Lenzetto to the breasts or any area near to the breasts. If you have difficulty applying to your forearm, apply to your inner thigh
- B. Make sure that the skin where you want to spray the medicine is clean and dry
- C. To apply your daily dose, take off the plastic cover, hold the container upright and rest the plastic cone flat against the skin
- D. You may need to move your arm or move the cone part of the container on the arm so that there are no gaps between the cone and your skin
- E. Press the button right down one time

3 Applying additional sprays



- A. If you have been prescribed two sprays, move the cone along your arm so that it is beside the area you have already sprayed. Make sure that the second spray does not overlap the area of the first spray. Press the button right down one time
- B. If three sprays have been prescribed, move the cone along your arm again ensuring that it does not overlap the sprayed areas, and press the button right down one time
- C. If your second or third spray will not fit the same inner forearm, you can also spray onto your other inner forearm
- D. Lenzetto should be sprayed in the same position(s) along the inner forearm each day

4 After application



- A. When you have finished using Lenzetto, always put the cover back on the container
- B. Let the spray dry for at least two minutes before getting dressed and at least 60 minutes before bathing or washing. If you get the spray on another area of your skin like your hands, wash that area of your skin with soap and water right away
- C. Do not massage or rub Lenzetto into the skin
- D. Do not allow other people to touch the area of skin you have sprayed. Cover the area with clothing once the spray has dried (2 minutes after application), if required. If another person (special care for children) accidentally touches the area of your skin where you sprayed Lenzetto, tell that person to wash the area of their skin with soap and water right away. Young children who accidentally come into contact with the area where Lenzetto was sprayed, may show unexpected signs of puberty (for example, breast budding). In most cases the symptoms will disappear when children are no longer exposed to estradiol spray. Contact your healthcare provider if any signs and symptoms (breast development or other sexual changes) in a child that may have been exposed accidentally to estradiol spray.

TRACK
YOUR
TREATMENT
(See page 12)

HOW DO I TRACK MY TREATMENT?

Do not dispose of your carton.
The tracker can be found on the side panel of the Lenzetto carton.



Before a new applicator is used for the first time, the pump should be primed by spraying three times with the cover on.

1. To track each of the 3 **priming sprays**, you should mark each primed spray with an "x" in the table.



Not actual pack.
Illustration only.

Mark each expelled spray with an "x" in the table below.
"0" is for the priming sprays.

	X	0	0				
1		1	2	3			
2	X	2	3	4	5	6	7
3		9	10	11	12	13	14
4		16	17	18	19	20	21
5		23	24	25	26	27	28
6		30	31	32	33	34	35
7		38	39	40	41	42	
8		45	46	47	48	49	
9		52	53	54	55	56	

KEEP THE CARTON

2. To track the **daily dose**, you should mark each expelled spray with an "x" in the table.

E.g., if you have been prescribed 2 sprays per day:
Day 1 - Cross boxes 1 and 2 after dosing. Day 2 - Cross boxes 3 and 4 after dosing.
Continue until all 56 sprays are used from the device.

HOW MANY SPRAYS DOES LENZETTO HAVE?



Lenzetto delivers 56 sprays after preparation (priming). Mark the dose table on the carton to keep track of the number of sprays you have used. Remember to get your next device just before or as soon as you have used the last dose of your current one, so there is no gap in your treatment.

Do not use the Lenzetto device for more than the 56 sprays, even if it is not completely empty. Do not use it after the expiry date which is stated on the carton and the label of the device.

1 spray per day - The container will last 56 days

2 sprays per day - The container will last 28 days

3 sprays per day - The container will last 18 days

If you are using 3 sprays of Lenzetto each day, be sure to check your tracker at the end of the container's 18th day to confirm whether you have any sprays remaining. If you do, to avoid wastage, please be sure to use these on the following day before moving onto a new container.

WHAT SHOULD I BE AWARE OF?

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

Do not take Lenzetto and talk to your doctor:

- If you have or have ever had breast cancer, or if you are suspected of having it
- If you have or have ever had any cancer which is sensitive to oestrogens, such as cancer of the lining of your womb (*endometrium*), or if you are suspected of having it
- If you have any unexplained vaginal bleeding
- If you have excessive thickening of the lining of your womb (*endometrial hyperplasia*) that is not being treated
- If you have or have ever had a blood clot in your vein (*thrombosis*), such as in the legs (*deep venous thrombosis*) or the lungs (*pulmonary embolism*)
- If you have a blood clotting disorder (such as protein C, protein S or antithrombin deficiency)
- If you have, or recently have had a disease caused by blood clots in the arteries, such as heart attack, stroke or angina
- If you have, or have ever had, a liver disease and your liver function tests have not returned to normal
- If you have a rare blood problem called "porphyria" which passes down in families (is inherited)
- If you are allergic to estradiol or any of the other ingredients of this medicine (which you can find in section 6 of the leaflet that comes with the pack of Lenzetto)
- Oestrogens may have an inhibitory affect on the anti-epileptic drug **lamotrigine**. This may reduce seizure control. Speak to your doctor if you have been prescribed lamotrigine.



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

WARNINGS AND PRECAUTIONS

Tell your doctor if you have ever had any of the following problems, before you start the treatment, as these may return or become worse during treatment with Lenzetto. If so, you should see your doctor more often for check-ups:

- Fibroids inside your womb
- Growth of womb lining outside your womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia)
- Increased risk of developing blood clots (see "Blood clots in a vein (thrombosis)" on page 14)
- Increased risk of getting an oestrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer)
- High blood pressure
- A liver disorder such as a benign liver tumour
- Diabetes
- Gallstones
- Migraine or severe headaches
- A disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE)
- Epilepsy
- Asthma
- A disease affecting the eardrum and hearing (otosclerosis)
- A very high level of fat in your blood (triglycerides)
- Fluid retention due to cardiac or kidney problems
- Hereditary and acquired angioedema

STOP USING LENZETTO AND SEE A DOCTOR IMMEDIATELY IF YOU NOTICE ANY OF THE FOLLOWING WHEN USING HRT:

- Any of the conditions mentioned in the “Do not take Lenzetto” section on page 14
- Yellowing of your skin or the whites of your eyes (jaundice) as these may be signs of a liver disease
- Swollen face, tongue and/or throat and/or difficulty swallowing or hives, together with difficulty breathing which are suggestive of an angioedema (allergic reaction)
- A large rise in your blood pressure (symptoms may be headache, tiredness, dizziness)
- Migraine-like headaches which happen for the first time
- 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

Note: *Lenzetto is not 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.*

Some medicines may interfere with the effect of Lenzetto. This might lead to irregular bleeding. This applies to the following medicines:

- Medicines for epilepsy
- Medicines for tuberculosis
- Medicines for HIV infection
- Herbal remedies containing St John’s wort
- Medicines for Hepatitis C virus (HCV) may cause an increase in liver function blood test results

Consult the leaflet in the pack of Lenzetto for more information and tell your doctor if you are using or have recently used any other medicine.

WHAT SHOULD I EXPECT?

You may experience a decrease in the frequency of moderate-to-severe hot flushes.

You will have a bleed once a month (known as withdrawal bleeding) while using Lenzetto, if it is combined with progestogen tablets. However, speak with your doctor if you have unexpected bleeding or drops of blood (spotting) besides your monthly bleeding, which:

- **Carries on for more than the first 6 months**
- **Starts after you have been using Lenzetto more than 6 months**
- **Carries on after you have stopped using Lenzetto**

Once you have started on Lenzetto you should see your doctor for regular check-ups (at least once a year). At these check-ups, **discuss the benefits and risks of continuing with Lenzetto with your doctor.**

You should also go for regular breast screening, as recommended by your doctor. For mammogram screening, it is important that you inform the nurse/healthcare professional who is actually taking the x-ray that you use hormone replacement therapy.



FREQUENTLY ASKED QUESTIONS

What if Lenzetto does not work for me?

Speak to your doctor if you are still being troubled by symptoms of menopause. They will aim to prescribe the lowest dose for as short as necessary to treat your symptoms, but can increase the dose up to a maximum of three sprays per day according to your individual needs.

If your symptoms remain unchanged at the maximum dose, speak with your doctor.

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

As mentioned above, your doctor will aim to start you on the lowest dose necessary to treat your symptoms. This means they will keep you on the lowest dose (1 spray) for the first four weeks of your course. However, the dose can be increased, if necessary, to control your symptoms. Make sure you speak to your doctor.

How long can I use Lenzetto for?

Speak with your doctor about your symptoms and frequency of risk assessments.

Lenzetto should only be taken 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 if I forget to use Lenzetto?

If you forget to use Lenzetto at your normal time, use the device as soon as you remember, and then use it as you normally would the next day.

If it is almost time for your next dose, just wait and apply the next dose as you normally would. If you forget one or more doses, one preparation spray with the cover on is needed before your next dose. Do not use a double dose to make up for a forgotten dose. Forgetting a dose may increase the likelihood of breakthrough bleeding and spotting. If you have any concerns, please speak with your doctor.

Will Lenzetto irritate skin?

Skin irritation with Lenzetto has been reported by 1.3% of users. Lenzetto contains ethanol, which may cause burning sensation if applied to damaged skin.

Can I wear sunscreen with Lenzetto?

If using sunscreen you should apply this before Lenzetto. You should also avoid using it on the part of the skin where you intend to spray the Lenzetto for at least 1 hour before or after. However, Lenzetto should be used with caution in extreme temperature conditions, such as sunbathing or sauna.

How do I store Lenzetto?

Keep Lenzetto out of the sight and reach of children.

Do not refrigerate or freeze the device. Do not store above 25 °C.

Lenzetto contains ethanol, which is flammable, so must be stored away from heaters, open flames, and other sources of ignition.

How should I dispose of Lenzetto once it's finished?

As there may be some medicine residue left in the device after the final spray, you should not dispose of Lenzetto yourself. Return finished devices to your pharmacy.

What if I have other questions about Lenzetto?

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

Lenzetto®

To access more information about Lenzetto, to download the patient support leaflet, and to watch the patient user video, please visit www.mylenzetto.co.uk and enter **Lenzetto1**.



Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme <https://yellowcard.mhra.gov.uk/>.

By reporting side effects, you can help provide more information on the safety of this medicine.



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