Package leaflet: information for the user

Lenzetto 1.53 mg/dose, transdermal spray, solution

estradiol

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

1. What is Lenzetto and what is it used for?

This medicine is a hormone replacement therapy (HRT). It contains the female hormone from the group of estrogens. This medicine is used in postmenopausal women whose last natural period was at least 6 months ago.
This medicine can also be used in women who have had surgery to remove the ovaries, as this immediately leads to menopause.

This medicine is a spray solution with a small amount of a drug called estradiol. When sprayed on the skin as prescribed, it passes through the skin and enters the bloodstream.

This medicine is used for:
Relief of symptoms occurring after menopause
During the period around menopause, the amount of estrogen produced by a woman's body decreases. This can cause symptoms such as a flushed face, neck, and chest ("hot flashes"). This medicine relieves these symptoms after menopause. You will only be prescribed this medicine if the symptoms severely disrupt your daily life.

This medicine is indicated for the treatment of symptoms of estrogen deficiency after menopause; when menstruation has stopped due to menopause. Symptoms of estrogen deficiency include hot flashes (sudden heat and sweating all over the body), sleep problems, irritability, and vaginal dryness.

There is only limited experience of treatment in women over 65 years of age.

This medicine is not a contraceptive.

2. When should you not use this medicine or be extra careful with it?

Medical history and regular check-ups
The use of HRT involves risks that should be considered when deciding to start or continue treatment.

There is only limited experience of treatment in women with premature menopause (due to ovarian failure or surgery). If you have premature menopause, the risks of using HRT may be different. Discuss this with your doctor.

Before you start (or restart) HRT, your doctor will ask you questions about your medical history and your family's medical history. Your doctor may decide to perform a physical examination. This may include a breast exam and/or an internal exam if necessary.

Once you have started this medicine, you should regularly return to your doctor for check-ups (at least once a year). During these check-ups, discuss with your doctor the benefits and risks of continuing Lenzetto.

Follow your doctor's recommendations and have your breasts checked regularly.

When should you not use this medicine?
Do not use this medicine if any of the following apply to you. If you are unsure about anything, contact your doctor before using this medicine.

When should you not use this medicine?
- You have breast cancer, have had it, or suspect you have breast cancer.
- You have a type of cancer that is sensitive to estrogens, such as cancer in the uterine lining (endometrium), or you suspect you have it.
- You have vaginal bleeding of unknown cause.
- You have an excessive thickening of the uterine lining (endometrial hyperplasia) that is not being treated.
- You have a blood clot in a vein (thrombosis), or have had one, e.g., in the legs (deep vein thrombosis) or in the lungs (pulmonary embolism).
- You have a blood clotting disorder (such as protein C, protein S, or antithrombin deficiency).
- You have a disease caused by blood clots in the veins, or have recently had such a disease, such as a heart attack, stroke, or angina.
- You have a liver disease, or have had one, and your liver function has not yet normalized.
- You have a rare blood disorder called “porphyria” that is passed on to future generations (hereditary condition).
- You are allergic to estradiol or any of the ingredients in this medicine. You can find these ingredients in section 6.

If one or more of the above situations occur for the first time while using this medicine, you should stop using it immediately and contact your doctor right away.

When should you be extra careful with this medicine?
Contact your doctor or pharmacist before using this medicine.

Tell your doctor before starting treatment if you have ever had any of the following problems, as they may return or worsen during treatment with this medicine. If this is the case, you should see your doctor more often for check-ups:

- a benign tumor in the uterus (also called a 'fibroid')
- a condition where the uterine lining is also found outside the uterus (endometriosis) or a history of abnormal growth of the uterine lining (endometrial hyperplasia).
- increased risk of developing blood clots (see "Blood clots in a vein (thrombosis)");
- increased risk of developing an estrogen-sensitive type of 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 tumor;
- diabetes;
- gallstones;
- migraine or severe headache;
- a condition of the immune system that affects multiple organs in the body
- (systemic lupus erythematosus, SLE);
- epilepsy;
- asthma;
- a disease that affects the eardrum and hearing (otosclerosis);
- a severely elevated fat concentration in the blood (triglycerides);
- fluid retention as a result of heart or kidney problems;
- hereditary and acquired angioedema.

Stop using this medicine and contact a doctor immediately if you notice the following during HRT:

- one or more of the conditions described in the section "When should you not use this medicine?";
- yellowing of the skin or the whites of the eyes (jaundice). These may be signs of a liver disorder;
- swelling of the face, tongue and/or throat and/or difficulty swallowing or a skin rash with pink bumps and severe itching (hives or urticaria), along with difficulty breathing; these symptoms indicate angioedema;
- a large increase in blood pressure (possible symptoms are headache, fatigue, dizziness);
- migraine-like headache that you have 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 breathing.

See "Blood clots in a vein (thrombosis)" for more information.

Note: This medicine is not a contraceptive. If your last menstrual period was less than 12 months ago, or if you are under 50 years old, you should use additional contraception to prevent pregnancy. Consult your doctor for advice.

HRT and cancer

Excessive thickening of the uterine lining (endometrial hyperplasia) and cancer in the uterine lining (endometrial cancer).
Use of HRT with estrogen only increases the risk of excessive thickening of the uterine lining (endometrial hyperplasia) and cancer in the uterine lining (endometrial cancer).

Taking progestogen alongside the estrogen for at least 12 days of the 28-day cycle prevents this additional risk. Your doctor will therefore also prescribe a progestogen if you still have your uterus. If your uterus has been removed (a hysterectomy), you should discuss with your doctor whether it is safe to use this medicine without progestogen.

In women who still have their uterus and do not use HRT, endometrial cancer is diagnosed in an average of 5 out of 1,000 users aged between 50 and 65 years.

In women aged 50 to 65 years who still have their uterus and use HRT with estrogen only, 10 to 60 out of 1,000 are diagnosed with endometrial cancer (i.e., 5 to 55 extra cases), depending on the dose and duration of use.

This medicine contains a higher dose of estrogen than other HRT products with estrogen only. The risk of endometrial cancer when using this medicine together with a progestogen is unknown.

Unexpected bleeding
Once a month you will have a bleeding (called withdrawal bleeding) when using Lenzetto in combination with sequentially dosed progestogen. However, if you have unexpected bleeding or light bleeding (spotting) in addition to the monthly bleeding that:
- persists for more than the first 6 months;
- starts after you have used this medicine for more than 6 months;
- persists after stopping this medicine;

you should contact your doctor as soon as possible.

Breast cancer
Research has shown that the use of hormone replacement therapy (HRT) with an estrogen-progestogen combination or HRT with estrogen alone increases the risk of breast cancer. The extra risk depends on how long you use HRT. The extra risk occurs after 3 years of use. After stopping HRT, the extra risk will decrease again, but if you have used HRT for more than 5 years, the extra risk may persist for 10 years or longer.

Comparison:
Of the women aged 50 to 54 who do not use HRT, an average of 13 to 17 per 1,000 women will develop breast cancer over a 5-year period.
Of the women aged 50 who use HRT with estrogen alone for 5 years, there will be 16-17 cases per 1,000 users (i.e., 0 to 3 extra cases).
Of the women aged 50 who start HRT with an estrogen-progestogen combination over a 5-year period, there will be 21 cases per 1,000 users (i.e., 4 to 8 extra cases).

Of the women aged 50 to 59 who do not use HRT, an average of 27 per 1,000 women will develop breast cancer over a 10-year period.

Of the women aged 50 who use HRT with estrogen alone for 10 years, there will be 34 cases per 1,000 users (i.e., 7 extra cases).
Of the women aged 50 who use HRT with an estrogen-progestogen combination for 10 years, there will be 48 cases per 1,000 users (i.e., 21 extra cases).

Check your breasts regularly. Contact your doctor if you notice changes such as:
- dimpling of the skin,
- change in the nipple,
- lumps that you see or feel.

You are also advised to attend mammography programs if offered. For mammography screening, it is important that you inform the nurse/healthcare provider taking the X-ray that you are using HRT, as this medication can increase the density of your breasts, which may affect the screening result. Where breast density is higher, not all lumps may be detected on the mammogram.

Ovarian cancer
Ovarian cancer is rare, much rarer than breast cancer. A slight increase in the risk of ovarian cancer has been reported with the use of estrogen therapy or a combination of estrogen/progestogen HRT.

The risk of ovarian cancer depends on age. Of the women aged 50 to 54 who do not use HRT, about 2 in 2,000 women will be diagnosed with ovarian cancer over a 5-year period. Among women who have used HRT for 5 years, there are about 3 cases per 2,000 users (i.e., about 1 extra case).

Effect of HRT on heart and circulation

Blood clots in a vein (thrombosis)
The risk of blood clots in the veins is about 1.3 to 3 times higher in HRT users than in non-users, especially during the first year of use.

Blood clots can have serious consequences, and if a blood clot reaches the lungs, it can cause chest pain, shortness of breath, fainting, or even death.

You are more likely to get a blood clot in a vein as you get older and if any of the following situations apply to you. Tell your doctor if any of these situations apply to you:
- You cannot walk for a long time due to major surgery, injury, or illness (see also section 3 “If you need to have surgery”).
- You are very overweight (BMI > 30 kg/m^2).
- You have a blood clotting disorder that requires long-term treatment with a medicine used to prevent blood clots.
- Someone in your immediate family has ever had a blood clot in a leg, lung, or other organ.
- You have systemic lupus erythematosus - SLE (chronic autoimmune disease where the body attacks its own cells, causing inflammation in various organs).
- You have cancer.

See “Stop using this medicine and contact a doctor immediately” for signs of a blood clot.

In women aged 50 to 60 who do not use HRT, it is expected that over a period of 5 years, an average of 4 to 7 out of 1,000 will develop a blood clot in a vein.

In women aged 50 to 60 who have used HRT with estrogen and progestogen for more than 5 years, there will be 9 to 12 cases out of 1,000 users (i.e., 5 extra cases).

In women aged 50 to 60 who have had their uterus removed and have used HRT with estrogen only for more than 5 years, there will be 5 to 8 cases out of 1,000 users (i.e., 1 extra case).

Heart disease (heart attack)
There is no evidence that HRT can prevent a heart attack.

Women over 60 who use HRT with estrogen and progestogen have a slightly higher risk of heart disease than those who do not use HRT.

For women who have had their uterus removed and use HRT with estrogen only, there is no increased risk of developing heart disease.

Stroke
The risk of stroke is about 1.5 times higher in HRT users than in those who do not use HRT. The additional number of strokes due to HRT use increases with age.

For comparison: In women aged 50 to 60 who do not use HRT, it is expected that over a period of 5 years, 8 out of 1,000 will have a stroke. In women aged 50 to 60 who use HRT, there will be 11 cases out of 1,000 users over 5 years (i.e., 3 extra cases).

Other conditions
HRT does not prevent memory loss. There is some evidence that women who start HRT after the age of 65 have a higher risk of memory loss. Contact your doctor for advice.

Children
Estradiol spray can accidentally be transferred from the skin to other people. Do not let others, especially children, come into contact with the exposed part of your skin and cover the area if necessary after the spray has dried. If a child comes into contact with the skin surface where estradiol has been sprayed, wash the child's skin as soon as possible with water and soap. Due to the transfer of estradiol, young children may show signs of puberty that are not expected (e.g., breast budding). In most cases, the symptoms will disappear when children are no longer exposed to estradiol spray. Contact your healthcare provider if you notice signs and symptoms (breast development or other sexual changes) in a child who may have been accidentally exposed to estradiol spray.

Are you using any other medicines?
Are you using any other medicines besides Lenzetto, have you recently done so, or is there a possibility that you will use other medicines in the near future? If so, tell your doctor.

Some medicines can interfere with the action of this medicine. This can lead to irregular bleeding. This applies to the following medicines:
- medicines for epilepsy (e.g., phenobarbital, phenytoin, and carbamazepine);
- medicines for tuberculosis (e.g., rifampicin, rifabutin);

- medicines for HIV infection (e.g., nevirapine, efavirenz, ritonavir, and nelfinavir);
- herbal medicines containing St. John's wort (Hypericum perforatum).

HRT can affect the action of some other medicines:
- a medicine for epilepsy (lamotrigine), as this can increase the frequency of seizures;
- medicines for treating a hepatitis C virus (HCV) infection (such as the combination treatments ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin; glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir can cause an increase in a liver enzyme (ALT, a liver function blood test) in women using combined hormonal contraceptives with ethinylestradiol. Lenzetto contains estradiol instead of ethinylestradiol. It is not known whether an increase in the ALT liver enzyme can also occur when Lenzetto is used with this HCV combination treatment.

Are you taking any other medicines, including over-the-counter medicines, herbal medicines, or other natural products, or have you done so recently? If so, tell your doctor or pharmacist. Your doctor will advise you.

Laboratory tests
If you need to have blood tests, tell your doctor or the laboratory staff that you are using this medicine, as this medicine can affect the results of some tests.

Pregnancy and breastfeeding
This medicine is intended only for women who have passed menopause. If you become pregnant, you should stop using this medicine and contact your doctor.

Do not use this medicine if you are breastfeeding.

Driving and using machines
This medicine has no known effect on the ability to drive or use machines.

Lenzetto contains alcohol
This medicine contains 65.47 mg of alcohol (ethanol) per dose, equivalent to 72.74% w/v (weight per volume).
This medicine may cause a burning sensation on your skin if your skin is damaged.
Liquids containing alcohol are flammable. Keep away from fire. Avoid open flames, a burning cigarette, or devices that may be hot (such as hairdryers) while spraying this medicine on your skin, and until the spray has dried.

3. How to use this medicine?

Always use this medicine exactly as your doctor has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

Your doctor will try to prescribe the lowest dose to treat your symptoms for as short a time as necessary. During treatment, your doctor may adjust the dose to your personal needs. Talk to your doctor if you think this dose is too strong or not strong enough.

If you have not had a hysterectomy (surgery to remove your uterus), your doctor will give you tablets with another hormone, progestogen, to counteract the effects of estrogens on your

uterine lining. Your doctor will explain how to take these tablets. At the end of the treatment with progestogen, a withdrawal bleed may occur. (See the section 'Unexpected bleeding'.)

If you need to undergo surgery
If you need to undergo surgery, tell the surgeon that you are using Lenzetto. You may need to stop using Lenzetto 4 to 6 weeks before the surgery to reduce the risk of blood clots (see section 2. Blood clots in a vein). Ask your doctor when you can start using Lenzetto again.

Where to apply this medicine
The spray should be applied to the inside of dry and healthy skin on the forearm. If this is not possible, it should be applied to the inside of the thigh. Do not apply this product to the breasts or near the breasts.

How to apply this product
Before using a new bottle for the first time, the sprayer must be prepared for use by priming it three times with the cap on. The bottle should be held upright, as shown in figure 1. Press the button straight down three times with your thumb or forefinger with the cap on. The medicine is now ready for use.

Do NOT prepare the sprayer for each dose; do this only when a new bottle is first used. If you miss one or more doses, prepare the sprayer for use according to the instructions described in the section "If you forget to use this product".

Ensure that the skin where you want to apply the medicine is healthy, clean, and dry.

How to apply your daily dose.

To apply your daily dose, remove the plastic cap, hold the bottle upright, and let the plastic funnel rest flat against the skin. (Figure 2.)

You may need to move your arm or the funnel-shaped part of the bottle so that the funnel rests completely against the skin, without gaps between the funnel and your skin.

Press the actuator button straight down once. It should always be fully pressed and held down before releasing.

If a second spray is needed, move the funnel next to the area already sprayed. Press the button straight down once.

If a third spray is needed, move the funnel again, and press the buttonstraight down once.

If there is no room on the inside of the same forearm for the second or third spray, you may also use the inside of your other forearm. If you have difficulty placing the funnel on the inside of the forearm as shown in figure 3, or if it is difficult for you to use the forearms, you can use the inside of your thigh.

Always replace the cap on the bottle after using this product. (Figure 4.)

When used according to the instructions, regardless of the spray form or pattern on the skin, each spray will deposit the same amount of the ingredient on the skin.

Allow the spray to dry for at least 2 minutes before dressing, and at least 60 minutes before showering or washing. If you get this product on another area of the skin, such as your hands, wash that area immediately with water and soap.

This product should not be used on open or damaged skin.

Do not massage or rub this product into the skin.

Do not let others touch the skin area where the spray has been applied until the spray has dried, and cover it with clothing if necessary 2 minutes after the spray is administered. If others (especially a child) accidentally touch the skin sprayed with this product, tell them to wash the area immediately with water and soap.

How much of this product you should use
Your doctor will likely start with the lowest dose (one spray per day) and you should discuss with your doctor how well the medication is working for you. If necessary, your doctor may increase the dose to two sprays per day. The maximum daily dose is 3 sprays.

How often you should use this medication
The total number of sprays (one spray is one dose) prescribed by your doctor should be applied at the same time each day.

How long you should continue with this medication
Talk to your doctor every 3-6 months about how long you should continue with this medication. You should only use this medication for the period needed to relieve hot flashes associated with menopause.

Other useful information
Sunscreen can reduce the absorption of estrogen from this medication.
Do not use sunscreen on the area of skin where you apply Lenzetto. However, if you need to use sunscreen, apply it at least 1 hour before using Lenzetto.

In extreme temperatures, such as in the sauna or sunbathing, this medication should be used with caution.

There is a limited amount of data available suggesting that the rate and extent of absorption of this medication may decrease in overweight and obesity. Discuss this with your doctor. During treatment, your doctor may adjust the dose to your personal needs.

Have you used too much of this medication?
If you have used too much of this medication, or children have accidentally used it, contact your doctor or hospital for advice regarding the risk and what to do.

Belgium: If you have used too much of Lenzetto, contact your doctor, pharmacist, or the Poison Control Center (070/245.245) immediately.

If you have used too much of this medication, you may feel nauseous, vomit, and experience withdrawal bleeding (an unusual vaginal bleeding).

Have you forgotten to use this medication?
If you have forgotten to use this medication at the usual time, apply it as soon as you remember, and use it the next day at the usual time. If it is almost time for your next dose, you can wait and apply it at the usual time. If one or more doses are missed, a priming spray in the cap is necessary. Do not take a double dose to make up for a missed dose. Missing a dose may increase the chance of breakthrough bleeding and spotting.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

If you stop using this medication
Your doctor will explain how to stop using this medication when the treatment is finished.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

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

The following conditions have been reported more frequently in women using HRT than in women not using HRT:
- breast cancer;
- abnormal growth or cancer in the lining of the womb (endometrial hyperplasia or endometrial cancer);
- ovarian cancer;
- blood clots in the veins of the legs or lungs (venous thromboembolism);
- heart disease;
- stroke;
- gallbladder disease;
- high blood pressure; - liver problems;
- high blood sugar levels;
- possible memory loss if HRT is started after the age of 65. See section 2 for more information about these side effects.

Some side effects can be serious.
You should seek immediate medical attention if you experience the following symptoms:
- sudden chest pain;
- chest pain that spreads to your arm or neck;
- breathing difficulties;
- painful swelling and redness of the legs;
- yellowing of the eyes and face (jaundice);
- unexpected vaginal bleeding (breakthrough bleeding) or light blood loss (spotting) after using Lenzetto for some time or after stopping treatment;
- breast changes such as dimpling of the breast skin, changes in the nipple, lumps you can see or feel;

- painful menstruations;
- dizziness or fainting;
- changes in speech ability;
- changes in vision;
- migraine-like headache without a clear cause.

Are you experiencing a lot of discomfort from a side effect? Or do you have a side effect that is not listed in this leaflet? Then contact your doctor or pharmacist.

The following side effects were reported with Lenzetto:

Common side effects (occur in less than 1 in 10 users)
Headache, abdominal pain, nausea, rash, itching (pruritus), irregular uterine bleeding or vaginal bleeding including light blood loss (spotting), tender breasts, painful breasts, weight gain or loss.

Uncommon side effects (occur in less than 1 in 100 users) Hypersensitivity reactions, depression, insomnia (difficulty sleeping), dizziness, vertigo with balance disorder, visual disturbances, palpitations, diarrhea, digestive difficulties (dyspepsia), increased blood pressure, painful, reddish skin nodules (erythema nodosum), general or localized rash or skin bumps (hives), skin irritation, swelling due to fluid retention (edema), muscle pain, breast discoloration, breast discharge, small growths (polyps) in the uterus or cervix, thickening of the uterine lining (endometrial hyperplasia), ovarian cysts, inflammation of the genital organs (vaginitis), increased levels of liver enzymes and cholesterol in the blood, pain in the forearm.

Rare side effects (occur in less than 1 in 1,000 users) Anxiety, increase or decrease in sex drive, migraine, intolerance to contact lenses, bloated abdomen, vomiting, increased body hair, (youth) acne, muscle cramps, painful menstruation, premenstrual-like syndrome, enlarged breasts, fatigue.

Other side effects, with the frequency “unknown” (frequency cannot be determined with the available data), have been reported after this medicine was marketed: hair loss (alopecia), dark spots on the skin, also called “pregnancy mask”, especially on the face (melasma), skin discoloration.

The following side effects were reported with other HRTs:
Severe allergic reactions causing swelling in the face or throat (angioedema), severe allergic reactions causing breathing problems or dizziness cause (anaphylactic/anaphylactoid reactions), glucose intolerance, depression, mood disorders, irritability, worsening of chorea - St. Vitus' dance (jerky movements of the face, arms, and legs), worsening of epilepsy, dementia, worsening of asthma, gallbladder disease, yellowing of the skin (jaundice), inflammation of the pancreas, benign tumor (neoplasia) of the smooth muscle of the uterus, various skin conditions: skin discoloration – especially on the face or neck – known as “pregnancy mask” (melasma or also called chloasma), painful reddish skin nodules (erythema nodosum), rash with target-shaped redness or sores (erythema multiforme), rash with bleeding (hemorrhagic rash), hair loss, joint pain, milk discharge from the breasts, lumps in the breasts, enlargement of benign tumor (neoplasia) of the smooth muscle of the uterus, changes in discharge from the cervix, changes in the lining of the cervix, vaginal inflammation, vaginal yeast infections (vaginal candidiasis), abnormally low concentration of calcium in the blood.

Reporting side effects
If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via

Belgium:
Federal Agency for Medicines and Health Products, Vigilance Division, P.O. Box 97, B-1000 Brussels Madou. Website: www.eenbijwerkingmelden.be, email: adr@fagg.be.

Luxembourg:
Centre Régional de Pharmacovigilance de Nancy or Division of Pharmacy and Medicines of the Health Directorate. Website: www.guichet.lu/pharmacovigilance.

Netherlands:
Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl.

By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the box and the label on the bottle.
It states a month and a year. The last day of that month is the expiry date. Use this medicine within 56 days after opening.

Do not store in the refrigerator or freezer.
Store below 25°C.
Contains flammable ethanol. Keep away from heat sources, open flames, and other ignition sources.

Do not flush medications down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medications you no longer use. They will be destroyed responsibly and will not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?
- The active substance in this medicine is estradiol (as estradiol hemihydrate). Each spray contains 1.53 mg estradiol (equivalent to 1.58 mg estradiol hemihydrate).
- The other substances in this medicine are octisalate and ethanol 96%.

What does Lenzetto look like and what is in the package?
Lenzetto is a spray for transdermal use with a solution of estradiol and octisalate in ethanol. It is supplied in a bottle with a dosing pump.

Lenzetto is packaged in a plastic container with a plastic cap. Inside the plastic container is a glass bottle containing 6.5 ml of solution, which is enough for 56 sprays of 90 microliters after it is prepared for use. Mark each spray done in the table on the box. Each spray contains 1.53 mg estradiol.

Do not use a Lenzetto bottle more than the number of sprays indicated on the label, even if the bottle is not completely empty.

Package sizes:
One plastic container, 6.5 ml (56 sprays)
Three plastic containers, 3x6.5 ml (3x56 sprays)

Not all mentioned package sizes are marketed.

Marketing authorization holder:
Gedeon Richter Plc.
Gyömrői út 19-21
H-1103 Budapest
Hungary

Manufacturer:
Gedeon Richter România S.A.
Strada Cuza Vodă 99-105
540306 Târgu-Mureş
Romania

Gedeon Richter Plc.
Gyömrői út 19-21
H-1103 Budapest
Hungary

Marketing authorization number:
Belgium: BE478426 - Dispensing method: Prescription only
Luxembourg: 2016040053
Netherlands: Registered under: RVG 114597

This medicine is registered in EEA member states under the following names:

Belgium	Lenzetto
Bulgaria	Lenzetto
Denmark	Lenzetto
Germany	Lenzetto
Estonia	Lenzetto
Finland	Lenzetto
Greece	Lenzetto
Hungary	Lenzetto
Ireland	Lenzetto
Iceland	Lenzetto
Italy	Lenzetto
Croatia	Lenzetto

Latvia	Lenzetto
Lithuania	Lenzetto
Luxembourg	Lenzetto
Malta	Lenzetto
Netherlands	Lenzetto
Norway	Lenzetto
Poland	Lenzetto
Romania	Lenzetto
Slovenia	Lenzetto
Slovakia	Lenzetto
Spain	Lenzetto
Czech Republic	Lenzetto
United Kingdom	Lenzetto
Sweden	Lenzetto

This leaflet was last approved in September 2025

For all information regarding this medicine, contact the local representative of the marketing authorization holder:

Gedeon Richter Benelux bv-srl
Noordkustlaan 16A
1702 Groot-Bijgaarden
Belgium Tel: + 32 2 704 93 30
info.benelux@gedeonrichter.eu