

## **Package leaflet: Information for the user**

### **Lenzetto 1.53 mg/spray transdermal spray, solution**

estradiol

**Read all of this 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.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

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

#### **1. What Lenzetto is and what it is used for**

Lenzetto is a Hormone Replacement Therapy (HRT). It contains the female hormone oestrogen. Lenzetto is used in postmenopausal women with at least 6 months since their last natural period. Lenzetto can also be used in women who have had surgery to remove their ovaries as this causes instant menopause.

Lenzetto is a spray solution which contains small amounts of a medicine called estradiol. When sprayed onto the skin as directed, it passes through the skin into your bloodstream.

Lenzetto is used for:

##### **Relief of symptoms occurring after menopause**

During the menopause, the amount of the oestrogen produced by a woman's body drops. This can cause symptoms such as hot face, neck and chest ("hot flushes"). Lenzetto alleviates these symptoms after menopause. You will only be prescribed Lenzetto if your symptoms seriously hinder your daily life.

Lenzetto is indicated to treat oestrogen deficiency symptoms after menopause; when menstruation has ceased following menopause. Symptoms of oestrogen deficiency include hot flushes (sudden waves of heat and sweating in the whole body), sleeping problems, irritability and dryness of the vagina.

The experience in treating women older than 65 years is limited.

Lenzetto is not a contraceptive.

#### **2. What you need to know before you use Lenzetto**

##### **Medical history and regular check-ups**

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

The experience in treating women with a premature menopause (due to ovarian failure or surgery) is limited. If you have a premature menopause the risks of using HRT may be different. Please talk to your doctor.

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

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 with your doctor the benefits and risks of continuing with Lenzetto.

Go for regular breast screening, as recommended by your doctor.

### **Do not use Lenzetto**

if any of the following applies to you. If you are not sure about any of the points below, **talk to your doctor** before using Lenzetto.

Do not use Lenzetto

- if you have or have ever had **breast cancer**, or if you are suspected of having it;
- if you have **cancer which is sensitive to oestrogens**, such as cancer of the womb lining (*endometrium*), or if you are suspected of having it;
- if you have any **unexplained vaginal bleeding**;
- if you have **excessive thickening of the womb lining** (*endometrial hyperplasia*) that is not being treated;
- if 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*);
- 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 is passed down in families (is inherited);
- if you are **allergic** to estradiol or any of the other ingredients of this medicine (listed in section 6).

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**

Talk to your doctor or pharmacist before using Lenzetto.

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)");
- 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 use Lenzetto” section;
- yellowing of your skin or the whites of your eyes (jaundice). 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;
- 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.

For more information, see ‘Blood clots in a vein (thrombosis)’.

**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.

**HRT and cancer**

**Excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the lining of the womb (endometrial cancer).**

Using oestrogen-only HRT will increase the risk of excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the womb lining (endometrial cancer).

Taking a progestogen in addition to the oestrogen for at least 12 days of each 28 day cycle protects you from this extra risk. So your doctor will prescribe a progestogen separately if you still have your womb. If you have had your womb removed (a hysterectomy), discuss with your doctor whether you can safely take this product without a progestogen.

In women who still have a womb and who are not using HRT, on average, 5 in 1000 will be diagnosed with endometrial cancer between the ages of 50 and 65.

For women aged 50 to 65 who still have a womb and who take oestrogen-only HRT, between 10 and 60 women in 1000 will be diagnosed with endometrial cancer (i.e. between 5 and 55 extra cases), depending on the dose and for how long it is taken.

Lenzetto contains a higher dose of oestrogens than other oestrogen-only HRT products. The risk of endometrium cancer when using Lenzetto together with a progestogen is not known.

**Unexpected bleeding**

You will have a bleed once a month (so-called withdrawal bleed) while using Lenzetto if it is combined with sequentially dosed progestogen product. But, 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;

**see your doctor as soon as possible.**

### **Breast cancer**

Evidence shows that taking combined oestrogen-progestogen or oestrogen-only hormone replacement therapy (HRT) increases the risk of breast cancer. The extra risk depends on how long you use HRT. The additional risk becomes clear within 3 years of use. After stopping HRT the extra risk will decrease with time, but the risk may persist for 10 years or more if you have used HRT for more than 5 years.

Compare: Women aged 50 to 54 who are not taking HRT, on average, 13 to 17 in 1000 will be diagnosed with breast cancer over a 5-year period. For women aged 50 who start taking oestrogen-only HRT for 5 years, there will be 16-17 cases in 1000 users (i.e. an extra 0 to 3 cases).

For women aged 50 who start taking oestrogen-progestogen HRT for 5 years, there will be 21 cases in 1000 users (i.e. an extra 4 to 8 cases).

Women aged 50 to 59 who are not taking HRT, on average, 27 in 1000 will be diagnosed with breast cancer over a 10-year period. For women aged 50 who start taking oestrogen-only HRT for 10 years, there will be 34 cases in 1000 users (i.e. an extra 7 cases). For women aged 50 who start using oestrogen-progestogen HRT for 10 years, there will be 48 cases in 1000 users (i.e. an extra 21 cases).

### **Regularly check your breasts. See your doctor if you notice any changes such as:**

- dimpling of the skin
- changes in the nipple
- any lumps you can see or feel.

Additionally, you are advised to join mammography screening programs when offered to you. For mammogram screening, it is important that you inform the nurse/healthcare professional who is actually taking the x-ray that you use HRT, 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.

### **Ovarian cancer**

Ovarian cancer is rare — much rarer than breast cancer. The use of oestrogen-only or combined oestrogen-progestagen HRT has been associated with a slightly increased risk of ovarian cancer.

The risk of ovarian cancer varies with age. For example, in women aged 50 to 54 who are not using HRT, about 2 women in 2000 will be diagnosed with ovarian cancer over a 5-year period. For women who have been using HRT for 5 years, there will be about 3 cases per 2000 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 using it.

Blood clots can be serious, and if one travels to the lungs, it can cause chest pain, breathlessness, fainting or even death.

You are more likely to get a blood clot in your veins as you get older and if any of the following applies to you. Inform your doctor if any of these situations applies to you:

- you are unable to walk for a long time because of major surgery, injury or illness (see also section 3, If you need to have surgery).
- you are seriously overweight (BMI >30 kg/m<sup>2</sup>).

- you have any blood clotting problem that needs long-term treatment with a medicine used to prevent blood clots.
- if any of your close relatives has ever had a blood clot in the leg, lung or another organ.
- you have systemic lupus erythematosus (SLE).
- you have cancer.

For signs of a blood clot, see “Stop using Lenzetto and see a doctor immediately”.

Looking at women in their 50s who are not using HRT, on average, over a 5-year period, 4 to 7 in 1000 would be expected to get a blood clot in a vein.

For women in their 50s who have been using oestrogen-progestogen HRT for over 5 years, there will be 9 to 12 cases in 1000 users (i.e. an extra 5 cases).

For women in their 50s who have had their womb removed and have been using oestrogen-only HRT for over 5 years, there will be 5 to 8 cases in 1000 users (i.e. 1 extra case).

### **Heart disease (heart attack)**

There is no evidence that HRT will prevent a heart attack.

Women over the age of 60 years who use oestrogen-progestogen HRT are slightly more likely to develop heart disease than those not using any HRT.

For women who have had their womb removed and are using oestrogen-only therapy there is no increased risk of developing a heart disease.

### **Stroke**

The risk of getting stroke is about 1.5 times higher in HRT users than in non-users. The number of extra cases of stroke due to use of HRT will increase with age.

#### *Compare*

Looking at women in their 50s who are not using HRT, on average, 8 in 1000 would be expected to have a stroke over a 5-year period. For women in their 50s who are using HRT, there will be 11 cases in 1000 users, over 5 years (i.e. an extra 3 cases).

### **Other conditions**

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. Speak to your doctor for advice.

### **Children**

Estradiol spray can be accidentally transferred from the skin to other people. Do not allow others, especially children, to come into contact with the exposed area of your skin and cover the area, if needed, after the spray has dried. If a child comes in contact with the part of the skin where estradiol was sprayed on, wash the child’s skin with soap and water as soon as possible. Due to the estradiol transfer, young children may show signs of puberty that are not expected (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 you see any signs and symptoms (breast development or other sexual changes) in a child that may have been exposed accidentally to estradiol spray.

### **Other medicines and Lenzetto**

Tell your doctor if you are using, have recently used or might use any other medicines.

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

- Medicines for **epilepsy** (such as phenobarbital, phenytoin and carbamazepin)
- Medicines for **tuberculosis** (such as rifampicin, rifabutin)

- Medicines for **HIV infection** (such as nevirapine, efavirenz, ritonavir and nelfinavir)
- Herbal remedies containing **St John's Wort** (*Hypericum perforatum*)

HRT can affect the way some other medicines work:

- A medicine for epilepsy (lamotrigine), as this could increase frequency of seizures;
- Medicines for Hepatitis C virus (HCV) (such as combination regimen ombitasvir/paritaprevir/ritonavir with or without dasabuvir as well as regimen glecaprevir/pibrentasvir) may cause increases in liver function blood test results (increase in ALT liver enzyme) in women using CHCs containing ethinylestradiol. Lenzetto contains estradiol instead of ethinylestradiol. It is not known whether an increase in ALT liver enzyme can occur when using Lenzetto with this HCV combination regimen.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription, herbal medicines or other natural products. Your doctor will advise you.

### **Laboratory tests**

If you need a blood test, tell your doctor or the laboratory staff that you are using Lenzetto because this medicine can affect the results of some tests.

### **Pregnancy and breast-feeding**

Lenzetto is for use in postmenopausal women only. If you become pregnant, stop using Lenzetto and contact your doctor.

Do not use Lenzetto while you are breast-feeding.

### **Driving and using machines**

Lenzetto has no known effect on the ability to drive or use machines.

### **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.

## **3. How to use Lenzetto**

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

Your doctor will aim to prescribe the lowest dose to treat your symptom for as short as necessary. During the treatment your doctor may adjust the dose according to your individual needs. Speak 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 womb), your doctor will give you tablets containing another hormone called progestogen to offset the effects of oestrogens on the lining of your womb. Your doctor will explain to you how to take these tablets. Withdrawal bleeding may occur at the end of the progestogen treatment period. (See section "Unexpected bleeding")

### **If you need to have surgery**

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

### **Where to apply Lenzetto**

The spray should be applied to the dry and healthy skin of the inner forearm. If that is not possible, it should be applied on the inner thigh.

**Do not apply Lenzetto to the breasts or any area near the breasts.**

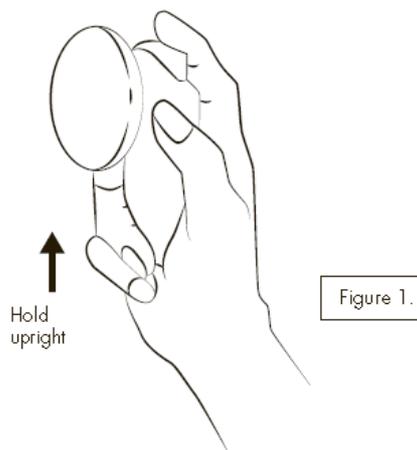
### **How to apply Lenzetto**

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

The container should be held upright as shown in Figure 1. With the cover on, press the button right down three times with your thumb or index finger.

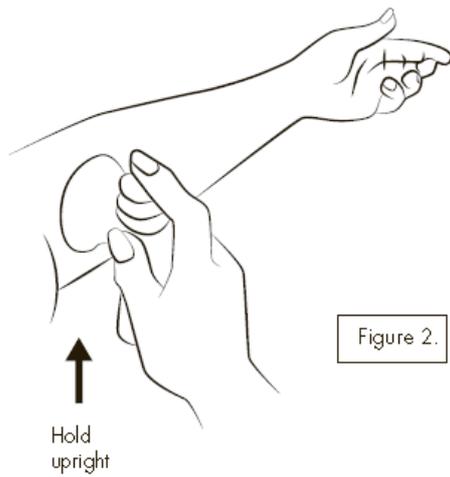
The medicine is now ready to use.

DO NOT prepare the applicator before each dose; only prepare the applicator once before starting to use a new container. If you miss one or more doses, prepare the applicator according to the instructions given in section “If you forget to use Lenzetto”.



**Make sure that the skin where you want to spray the medicine is healthy, clean and dry.**

How to apply your daily dose.



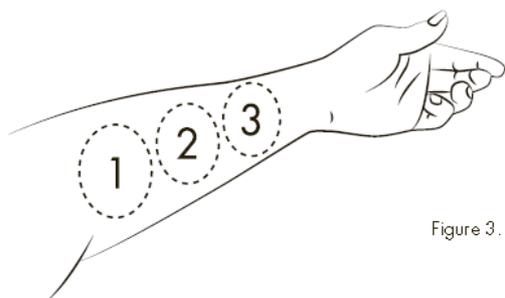
To apply your daily dose, take off the plastic cover, hold the container upright and rest the plastic cone flat against the skin. (Figure 2)

You may need to move your arm or move the cone part of the container on the arm so that the cone is flat against your skin and there are no gaps between the cone and your skin.

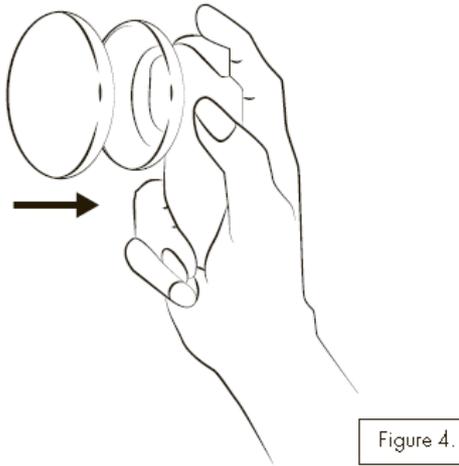
Press the actuator button right down once. It should be **pushed always fully** and held down before releasing.

If another spray is needed, move the cone along your arm so that it is beside the area you have already sprayed. Press the button right down one time.

If a third spray is needed, move the cone along your arm again and press the button right down one time.



If your second or third spray will not fit the same inner forearm, you may also spray onto your other inner forearm. If you have trouble putting the cone on your inner forearms as shown in Figure 3. or it is difficult for you to use it on the forearms, you may also spray onto the inner surface of your thigh.



When you have finished using Lenzetto, always put the cover back on the container. (Figure 4.)

If you use the product according to the instructions, irrespective of different spray shape or pattern on your skin each puff will deliver the same amount of ingredient on your skin.

Let the spray dry for at least **2** minutes before getting dressed and at least **60** minutes before bathing or washing. If you get Lenzetto spray on another area of your skin like your hands, wash that area of your skin with soap and water right away.

Lenzetto should not be used on broken or damaged skin.

Do not massage or rub Lenzetto into the skin.

**Do not allow other people to touch the area of the skin where the spray was sprayed until the spray has dried and cover with clothing 2 minutes after application of the spray if needed.** If another person (especially a child) 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.

#### **How much Lenzetto you should use**

Your doctor will probably start you on the lowest dose (one spray per day) and you should talk with your doctor about how well the medicine is working for you. If necessary, your doctor may increase your dose to two sprays per day. The maximum daily dose is 3 sprays.

#### **How often you will use Lenzetto**

The total number of sprays (dose(s)) that your doctor has prescribed for you should be applied at the same time each day.

#### **The period of time you will continue to use Lenzetto**

Talk to your doctor every 3-6 months about how long you should use Lenzetto for. You should only use Lenzetto for as long as you need it to provide relief from hot flushes associated with menopause.

#### **Other useful information**

Sunscreens can alter the absorption of oestrogen from Lenzetto.

Avoid using sunscreen on the part of the skin where you intend to spray Lenzetto. However, if you need to use sunscreen, it should be applied at least one hour prior to using Lenzetto.

Lenzetto should be used with caution under extreme temperature conditions, such as sauna or

sunbathing.

There is limited data suggesting that the rate and extent of absorption of Lenzetto may be reduced in overweight and obese women. Please talk to your doctor. During the treatment your doctor may adjust the dose according to your individual needs.

**If you use more Lenzetto than you should**

If you use more Lenzetto than you should, or if children have been using the medicine by accident, contact your doctor or the hospital to get an opinion of the risk and advice on action to be taken. If you use more Lenzetto than you should, you may feel sick, vomit and have withdrawal bleeding (unusual vaginal bleeding).

**If you forget to use Lenzetto**

If you forget to use Lenzetto at your normal time, spray the medicine on 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 primer spraying with the cover on is needed. 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 further questions about how to use this product, ask your doctor or pharmacist.

**If you stop using Lenzetto**

Your doctor will also explain how to stop using this medicine when your treatment is finished.

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

**4. Possible side effects**

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

The following diseases are reported more often in women using HRT compared to women not using HRT:

- breast cancer;
- abnormal growth or cancer of the lining of the womb (endometrial hyperplasia or cancer);
- ovarian cancer;
- blood clots in the veins of the legs or lungs (venous thromboembolism);
- heart disease;
- stroke;
- gall bladder disease;
- high blood pressure;
- liver problems;
- high blood sugar;
- probable memory loss if HRT is started over the age of 65.

For more information about these side effects, see Section 2.

**Some side effects can be serious.**

The following symptoms need immediate medical attention:

- sudden chest pain;
- pain in your chest that spreads to your arm or neck;
- breathing difficulties;
- painful swelling and redness in the legs;
- yellowing of the eyes and face (jaundice);
- unexpected vaginal bleeding (breakthrough bleeding) or spotting after using Lenzetto for some time or after you stop treatment;
- breast changes including dimpling of the breast skin, changes in the nipple, lumps that you can see or feel;

- painful menstrual periods;
- dizziness and faintness;
- changes in speech;
- changes in vision;
- unexplained migraine-like headaches.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The following side effects below have been reported with Lenzetto:

**Common side effects** (may affect up to 1 in 10 people)

Headache, abdominal pain, nausea, rash, pruritis (itching), irregular uterine bleeding or vaginal bleeding including spotting, breast tenderness, breast pain, weight increase or weight decrease.

**Uncommon side effects** (may affect up to 1 in 100 people)

Hypersensitivity reactions, depressed mood, insomnia (difficulty sleeping), dizziness, vertigo (a feeling of dizziness or “spinning”), visual disturbances, palpitations (feeling your heartbeat), diarrhoea, dyspepsia (indigestion), increased blood pressure, erythema nodosum (characterized by painful reddish skin nodules), hives (general or localised rash or lumps), skin irritation, swelling due to fluid retention (oedema), muscle pain, breast discolouration, breast discharge, polyps (small growths) in the uterine or cervix, endometrial hyperplasia, ovary cyst, inflammation of genitals (vaginitis), increased liver enzymes and blood cholesterol, underarm pain.

**Rare side effects** (may affect up to 1 in 1000 people)

Anxiety, decrease or increase in sexual drive, migraine, intolerance to contact lenses, bloating, vomiting, increased body hair, acne, muscle cramps, painful menstruation, premenstrual like syndrome, breast enlargement, fatigue.

**Other side effects**, with frequency “not known” (frequency cannot be estimated from the available data) have been reported with Lenzetto during post-marketing surveillance: hair loss (alopecia), chloasma (golden brown pigment patches, so called “pregnancy patches”, especially on the face), skin discolouration.

**The following side effects have been reported with other HRTs:**

Serious allergic reaction which causes swelling of the face or throat (angioedema), anaphylactoid/anaphylactic reactions (serious allergic reaction which causes difficulty in breathing or dizziness), glucose intolerance, depression, mood disturbances, irritability, exacerbation of chorea (St. Vitus’s dance), exacerbation of epilepsy, dementia, exacerbation of asthma, gall bladder disease, yellowing of the skin (jaundice), inflammation of the pancreas, benign neoplasm of the smooth muscle of the womb, various skin disorders: discolouration of the skin especially of the face or neck known as “pregnancy patches” (chloasma); painful reddish skin nodules (erythema nodosum); rash with target-shaped reddening or sores (erythema multiforme), haemorrhagic eruption, loss of hair, pain in a joint, secretion of milk from the breast, lumpiness in the breasts, increase in size of benign neoplasm of the smooth muscle of the womb, changes in the secretion and the inner lining of the cervix (“neck” of the womb), inflammation of the vagina, fungal infections in the vagina (vaginal candidiasis), abnormally low level of calcium in the blood.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly:

**for United Kingdom (Northern Ireland)**

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store

**for Ireland**

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

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

**5. How to store Lenzetto**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the label of the container. The expiry date refers to the last day of that month.

Use within 56 days of first use.

Do not refrigerate or freeze this medicine.

Do not store above 25 °C.

Contains ethanol which is flammable. Store away from heaters, open flames, and other sources of ignition.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information****What Lenzetto contains**

- The active ingredient is estradiol (as estradiol hemihydrate). Each spray contains 1.53 mg estradiol (equivalent to 1.58 mg estradiol hemihydrate).
- The other ingredients are octisalate and ethanol 96 %.

**What Lenzetto looks like and contents of the pack**

Lenzetto is a transdermal spray containing a solution of estradiol and octisalate in ethanol. It is provided with a metered dose pump.

Lenzetto is supplied as a plastic container with a plastic cover. There is a glass container inside, that contains 6.5 mL of solution and is designed to deliver 56 sprays of 90 microliter after priming. Mark the number of sprays made using the table on the carton. Each spray contains 1.53 mg estradiol.

Do not use each Lenzetto container for more than the labelled number of sprays even though the bottle may not be completely empty.

Pack sizes:

One plastic container 6.5 mL (56 sprays)

Three plastic containers 3x6.5 mL (3x56 sprays).

Not all pack sizes may be marketed.

**Marketing Authorisation Holder:**

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**Manufacturer:**

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