South Tyneside and Sunderland
Area Prescribing Committee

# Information leaflet for primary care: Lenzetto

**Background information**

Lenzetto is a transdermal unopposed oestrogen. Therefore, women with an intact uterus should have adjunct progesterone added.
This is prescribed in women following menopausal assessment. Women should start on the lowest dose. If symptoms persist the dose of Lenzetto should be increased to a maximum of 3 sprays.
First line therapy is usually oral due to lower cost and user preference. Transdermal oestrogen is associated with fewer risks than oral HRT at low doses

The patients most likely to benefit from Lenzetto are those currently on oral treatments.
Patients likely to find it most easy to transition onto sprays are likely to be those patients already on another transdermal product

Consider transdermal HRT for menopausal women who are at increased risk of VTE, including those with a BMI over 30 kg/m2. Also consider transdermal HRT in diabetic patients, patients with liver problems, and patients who experience side effects with oral treatment

**Formulary status**

GREEN

**Related NICE guidance**

NICE guideline NG23

**Licensed indication**

Hormone Replacement Therapy (HRT) for oestrogen deficiency symptoms in postmenopausal women (in women at least 6 months since last menses or surgical menopause, with or without a uterus).

The experience in treating women older than 65 years is limited

**Dosage and administration**

## Dose and Frequency:

1-3 metered dose sprays
1.53 mg/day - 4.59 mg/day

One metered-dose spray is administered once daily to the dry and healthy skin of the forearm as a starting dose. The dose may be increased to two metered-dose sprays daily to the forearm based on clinical response. Dose increase should be based on the degree of the woman's menopausal symptoms and should be made only after at least 4 weeks of continuous treatment with Lenzetto. The maximum daily dose is 3 metered-dose sprays (4.59 mg/day) to the forearm.
In women with an intact uterus, the product should be combined with a progestogen approved for addition to oestrogen treatment in a continuous - sequential dosing scheme: the oestrogen is dosed continuously. The progestogen is added for at least 12 to 14 days of every 28-day cycle, in a sequential manner

## Likely duration of treatment:

The duration of treatment will be a clinical decision, based on the symptoms of the individual patient vs risk. Ideally 2-3 years over peri-menopausal period.

**Contraindications**

- Known, past or suspected breast cancer;
- Known or suspected oestrogen-dependent malignant tumours (e.g. endometrial cancer);
- Undiagnosed genital bleeding;
- Untreated endometrial hyperplasia;
- Previous or current venous thromboembolism (deep venous thrombosis, pulmonary embolism);
- Known thrombophilic disorders (e.g. protein C, protein S, or antithrombin deficiency)
- Active or recent arterial thromboembolic disease (e.g. angina, myocardial infarction);
- Acute liver disease, or a history of liver disease as long as liver function tests have failed to return to normal;
- Porphyria;
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of SmPC

**Cautions**

In women with an intact uterus, the product should be combined with a progestogen approved for addition to oestrogen treatment in a continuous - sequential dosing scheme: the oestrogen is dosed continuously. The progestogen is added for at least 12 to 14 days of every 28-day cycle, in a sequential manner.

Reasons for immediate withdrawal of therapy. Therapy should be discontinued in case a contraindication is discovered and in the following situations: - Jaundice or deterioration in liver function - Significant increase in blood pressure - New onset of migraine-type headache – Pregnancy

Storage: Shelf life 3 years. Use within 56 days of first use. Special precautions for storage Do not refrigerate or freeze. Do not store above 25°C. Contains ethanol which is flammable. Store away from heaters, open flames, and other sources of ignition.

**Duration of treatment**

The duration of treatment will be a clinical decision, based on the symptoms of the individual patient vs risk. Ideally 2-3 years over peri-menopausal period.

**Drug interactions**

Hormone replacement therapy | Interactions | BNF content published by NICE

**Side effects**

Abdominal pain, Nausea, Rash, Pruritus, Breast pain, Breast tenderness, Uterine/Vaginal bleeding including spotting, Metrorrhagia

**Monitoring**

Monitoring not specifically required
Review is required at 3 month and annual follow up visit
Keep record of patients using Lenzetto.
Audit continuation, side effects, adverse reactions and patient experience of use of this HRT method.

**GP and specialist responsibilities**

Yearly review
Assess risk benefit profile
Advise tapered discontinuation after 2-3 years

**Cost**

£6.90 for 1 container of 8.1 mL transdermal spray solution, designed to deliver 56 sprays after priming. [4]

Estimated Annual Usage (per patient): 7 - 20 containers of 8.1 mL transdermal spray solution depending on dose used [1]

Monthly costs
1 metered spray = £3.45
2 metered spray =£6.90
3 metered sprays =£10.35

References


1. Lenzetto Summary of Product Characteristics UK, updated 12/06/2018

   https://www.medicines.org.uk/emc/product/11175/smpc

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4. Morton Terri L PhD et al. Steady-state pharmacokinetics following application of a novel transdermal estradiol spray in healthy postmenopausal women. J. Clin Pharmacol 2009; 49:1037-46

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6. Fait et al. The use of oestradiol metered-dose transdermal spray in clinical practice.

   https://www.tandfonline.com/doi/full/10.1080/13697137.2018.1504916

7. Kovacs G et al, Climacteric September 2016
   https://www.tandfonline.com/doi/full/10.1080/13697137.2016.1221919

8. Menopause-guideline-14-8-2017-APC-approved
   http://medicines.necsu.nhs.uk/guidelines/north-of-tyne-guidelines