

SERIOUS SHORTAGE PROTOCOL (SSP)

Reference Number: SSP028

- SSP 026 – Where the duration of treatment on the prescription is for more than 3 months of estradiol (Lenzetto®) 1.53mg/dose transdermal spray and supplies of estradiol (Lenzetto®) 1.53mg/dose transdermal spray are available.
- SSP 027– Where the duration of treatment on the prescription is for 3 months or less of estradiol (Lenzetto®) 1.53mg/dose transdermal spray, supplies of estradiol (Lenzetto®) 1.53mg/dose transdermal spray are unavailable, and substitution is deemed clinically appropriate.
- SSP 028 (**this SSP**) – Where the duration of treatment on the prescription is for more than 3 months of estradiol (Lenzetto®) 1.53mg/dose transdermal spray, supplies of estradiol (Lenzetto®) 1.53mg/dose transdermal spray are unavailable, and substitution is deemed clinically appropriate.

This SSP applies to the following medicine:

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| <p>Name of medicine (including strength and formulation)</p> | <p>Estradiol (Lenzetto®) 1.53mg/dose transdermal spray where the prescription is for more than 3 months of supply and supplies are unavailable.</p> <p>Where the prescription is for 3 months or less and supplies are unavailable, please refer to SSP027.</p> <p>Where the prescription is for more than 3 months and supplies are available, please refer to SSP026.</p> <p><u>Pharmacists must ensure that the patient’s prescriber and/or GP practice is notified when supplying a patient in accordance with this SSP as soon as practically possible, and within 3 working days. Please refer to ‘Outline of Operational Guidance for Dispensers in response to issue of a Serious Shortage Protocol’ on the BSO website for more information.</u></p> |
| <p>Legal category</p> | <p>POM</p> |

1. Details of medication to be supplied under this SSP

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| <p>Name of medicine (including formulation and strength) to be supplied</p> | <p>Estradiol patch – the strength of estradiol patch is to be determined by the patient’s current daily dosing regime of estradiol (Lenzetto®) 1.53mg/dose transdermal spray as set out in Annex A.</p> <p>Due to the nature of the substitution, an exact replication of the duration of treatment may not be possible. Supply must be made to the nearest patch. Pharmacists must use the equivalence quantities as set out in Annex A, where the various brands of estradiol patches are listed with the different dosing instructions.</p> |
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| Quantity of this formulation (if applicable) | <p>Total quantity supplied under this protocol to be limited to 3 months' supply of estradiol patches where the prescription for estradiol (Lenzetto®) 1.53mg/dose transdermal spray is for more than 3 months' supply. In line with Annex A, this should be a reasonable estimate where an exact equivalent dose is not possible due to the nature of the substitution.</p> <p>Dependent on the patient's current daily dose of estradiol (Lenzetto®) 1.53mg/dose transdermal spray, supply to the nearest quantity of estradiol patches according to Annex A.</p> |
| Substitution results in a change to whether the use is licenced | No |

Scope for which this Serious Shortage Protocol (SSP) applies

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| The SSP applies to the following parts of the UK | Northern Ireland |
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Clinical situation to which this Serious Shortage Protocol (SSP) applies

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| Scope of SSP | All brand and generically prescribed NHS and private prescriptions. |
| Criteria for inclusion | <ul style="list-style-type: none"> • The patient presents with a valid prescription (meeting the requirements of the Human Medicines Regulations 2012) for estradiol (Lenzetto®) 1.53mg/dose transdermal spray. • The patient/carer consents to receiving the medicine supplied under this SSP. • All patients aged 18 years of age or above. |
| Criteria for exclusion | <ul style="list-style-type: none"> • The patient presents with a prescription for a medicine other than estradiol (Lenzetto®) 1.53mg/dose transdermal spray. • The patient presents a prescription which is not valid. • The patient/carer does not consent to receiving the medicine(s) supplied under this SSP. • Where the pharmacist, using their professional judgement, determines that the patient is not suitable to receive alternative medicine under this SSP. • Known previous hypersensitivity or severe adverse reaction to estradiol patches or their excipients. See counselling below. • Known previous lack of efficacy to estradiol patches. See counselling below. |

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| | <ul style="list-style-type: none"> • Patients aged less than 18 years. • If the prescription for estradiol (Lenzetto®) 1.53mg/dose transdermal spray received is for more than 3 months and supplies are available, refer to SSP026. • If the prescription for estradiol (Lenzetto®) 1.53mg/dose transdermal spray received is for 3 months or less and supplies are not available, refer to SSP027. |
| <p>Cautions including any relevant action to be taken</p> | <ul style="list-style-type: none"> • Ensure that patients considered unsuitable for inclusion of SSP026, SSP027, SSP028 are promptly referred to their prescriber for review. • Using the prescription, clarify with patients their current daily dose of estradiol (Lenzetto®)1.53mg/dose transdermal spray to inform the decision to switch to the appropriate strength of estradiol patch (see Annex A for dose equivalence of estradiol (Lenzetto®)1.53mg/dose transdermal spray to estradiol patches and current availability). • Assure patients of the following: <ul style="list-style-type: none"> ○ the product they are being supplied in accordance with this SSP contains the same ingredient (estradiol) as Lenzetto® transdermal spray. ○ although the dosing schedule and formulation (spray to patch) is different, they will receive a near equivalent daily dose of estradiol that should manage their symptoms. ○ clinical experts in menopause have been consulted in the production of this SSP and have advised on this approach. • Ensure that patients who are supplied in accordance with this SSP are counselled by the pharmacist with regards to monitoring and managing potential side effects, such as: <ul style="list-style-type: none"> ○ Vaginal ‘breakthrough bleeding’; ○ Skin irritation due to patch; ○ Patches coming off or not adhering properly. ○ Further information on counselling can be found here (NICE guidance). • Patients who experience persistent side effects from patches supplied in accordance with this SSP should be promptly referred back to their prescriber. • Patients with an intact uterus should be advised that they should continue to take the progestogen component of their HRT regimen, even after switching to estradiol patches. • If patients have reported a history of local irritation to patches and can confidently identify the patch they used, then pharmacists should: <ul style="list-style-type: none"> ○ Assess whether the reaction to the first brand was severe or not by considering if there were any widespread skin reactions or systemic side effects such as shortness of breath, flushing of the face, etc. |

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| | <ul style="list-style-type: none"> ○ If the previous skin reaction was mild and local, seek consent from the patient to try another brand of patch, if available. ○ If the patient agrees to try an alternative brand of estradiol patches, advise them to remove the patch immediately if a problem occurs and see their GP. ○ If the previous reaction to patches was severe or the patient cannot identify which patch was tried previously, refer the patient to their prescriber. ● The dose equivalents in Annex A are subject to individual variations in absorption and metabolism. Patients who feel their symptom control has been affected by the switch after 8 weeks should be referred back to their prescriber. ● Ensure that the patient's prescriber and/or GP practice is notified of the current dose of estradiol (Lenzetto®) 1.53mg/dose transdermal spray as reported by the patient, and the strength and brand of estradiol patch supplied when supplying a patient in accordance with this SSP. |
| Special considerations for specific populations of patients | Particular care and caution should be taken to provide advice to patients who are considered at higher risk of experiencing the nocebo effect. Patients should be reassured as to the appropriateness and effectiveness of this alternative treatment as per the counselling points above. If there are significant concerns, refer the patient back to their prescriber for further advice. |
| Action to be taken if the patient is excluded | If a patient does not meet the criteria within this SSP then they should be referred back to their prescriber promptly. |
| Action to be taken if the patient or carer declines the supply | If a patient/carers declines to receive medicine under this SSP then they should be referred back to their prescriber promptly. |

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| Valid from: | 25 July 2022 |
| Expiry date: | 29 October 2022 |
| Reference number: | SSP028 |
| Version number: | 1.1 |

Any queries regarding the content of this SSP which was issued by the Department of Health – Northern Ireland should be forwarded to communitypharmacy@health-ni.gov.uk

Change history

| Version number | Change details | Date |
|----------------|---|------------|
| V1.1 | Expiry date extended to 29 October 2022 | 25/07/2022 |
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2. Conditions under which this Serious Shortage Protocol (SSP) will operate

- The decision to supply any medicine under this protocol rests with the individual registered pharmacist who must abide by the protocol.
- Whilst pharmacy staff may support the dispensing process of the protocol, this must be carried out under the supervision of the registered pharmacist.
- Pharmacists using this SSP must ensure that it is only used within its authorised dates and within the criteria set out within the SSP. Pharmacists must check that they are using the current version of the SSP, particularly when referring to a hard copy version. Amendments may become necessary prior to the published expiry date. Current versions of SSP templates can be found at www.hscbusiness.hscni.net/services/3063.htm
- Users must not alter, amend or add to the content of this document; such action will invalidate the SSP.

| Ministerial ratification by: | | | |
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| Name | Position | Signature | Date |
| Minister Robin Swann | DOH Minister |  | 25/07/2022 |

Annex A - Dose conversion of estradiol (Lenzetto®) 1.53mg/dose transdermal spray to estradiol patches including the brands covered by this SSP

| Current daily dosing regime of estradiol (Lenzetto®) 1.53mg/dose spray | Equivalent dose of estradiol patch | Patch options | Dosing | Quantity to supply |
|--|------------------------------------|---------------|-------------------------------------|--|
| 1 spray daily | 25 microgram patch | Evorel® | Apply one patch TWICE WEEKLY | For every 56 dose pack of Lenzetto® 1.53mg/dose transdermal spray supply 16 x Evorel® patches |
| 2 sprays daily | 50 microgram patch | Progynova TS® | Apply one patch WEEKLY | For every 56 dose pack of Lenzetto® 1.53mg/dose transdermal spray supply 4 Progynova TS® patches |
| | | FemSeven® | Apply one patch WEEKLY | For every 56 dose pack of Lenzetto® 1.53mg/dose transdermal spray supply 4 FemSeven® patches |
| | | Evorel® | Apply one patch TWICE WEEKLY | For every 56 dose pack of Lenzetto® 1.53mg/dose transdermal spray supply 8 Evorel® patches |

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| | | Estraderm MX® | Apply one patch TWICE WEEKLY | For every 56 dose pack of Lenzetto® 1.53mg/dose transdermal spray supply 8 Estraderm MX® patches |
| 3 sprays daily | 75 microgram patch | FemSeven® | Apply one patch WEEKLY | For every 56 dose pack of Lenzetto® 1.53mg/dose transdermal spray supply 3 Femseven® patches |
| | | Evorel® | Apply one patch TWICE WEEKLY | For every 56 dose pack of Lenzetto® 1.53mg/dose transdermal spray Supply 6 Evorel® patches |
| | | Estraderm MX® | Apply one patch TWICE WEEKLY | For every 56 dose pack of Lenzetto® 1.53mg/dose transdermal spray supply 6 Estraderm MX® patches |