SERIOUS SHORTAGE PROTOCOL (SSP)

Reference Number: SSP025

- SSP 020 – Where the duration of treatment on the prescription is for more than 3 months of estriol (Ovestin® 1mg) 0.1% cream and estriol (Ovestin® 1mg) 0.1% cream is available.
- SSP 024– Where the duration of treatment on the prescription is for 3 months or less of estriol (Ovestin® 1mg) 0.1% cream, supplies of estriol (Ovestin® 1mg) 0.1% cream are unavailable, and substitution is deemed clinically appropriate.
- SSP 025 **(this SSP)** – Where the duration of treatment on the prescription is for more than 3 months of estriol (Ovestin® 1mg) 0.1% cream, supplies of estriol (Ovestin® 1mg) 0.1% cream are unavailable, and substitution is deemed clinically appropriate.

This SSP applies to the following medicine:

Name of medicine (including strength and formulation)	Estriol (Ovestin® 1mg) 0.1% cream **where the prescription is for more than 3 months of supply and supplies are unavailable.** Where the prescription is for 3 months or less and supplies are unavailable, please refer to SSP024. Where the prescription is for more than 3 months and supplies are available, please refer to SSP020. **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.**
Legal category	POM

1. **Details of medication to be supplied under this SSP**

Name of medicine (including formulation and strength) to be supplied	Estriol 0.01% cream
Quantity of this formulation (if applicable)	Total quantity supplied under this protocol to be **limited** to 3 months' supply of estriol 0.01% cream where the prescription for Estriol (Ovestin® 1mg) 0.1% cream is for more than 3 months' supply. For every 15g pack of Ovestin® 1mg cream or estriol 0.1% cream, the following quantity must be supplied in accordance with this protocol:

	2 x estriol 0.01% cream (80g pack)
Substitution results in a change to whether the use is licenced	No

Scope for which this Serious Shortage Protocol (SSP) applies

The SSP applies to the following parts of the UK	Northern Ireland

Clinical situation to which this Serious Shortage Protocol (SSP) applies

Scope of SSP	All brand and generically prescribed NHS and private prescriptions.
Criteria for inclusion	• The patient presents with a valid prescription (meeting the requirements of the Human Medicines Regulations 2012) for estriol (Ovestin® 1mg) 0.1% cream. • The patient/carer consents to receiving the medicine supplied under this SSP. • All patients aged 18 years of age or above.
Criteria for exclusion	• The patient presents with a prescription for a medicine other than estriol (Ovestin® 1mg) 0.1% cream. • 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 estriol 0.01% cream or its excipients including allergies to soya or peanuts as estriol 0.01% cream contains peanut (arachis) oil. • Patients aged less than 18 years. • If the prescription for estriol (Ovestin® 1mg) 0.1% cream received is for more than 3 months and supplies are available, refer to SSP020. • If the prescription for estriol (Ovestin® 1mg) 0.1% cream received is for 3 months or less and supplies are not available, refer to SSP024
Cautions including any relevant action to be taken	• Ensure that patients considered unsuitable for inclusion of SSP020, SSP024 or SSP025 are promptly referred to their prescriber for further advice. • Assure patients of the following:

	○ the product they are being supplied in accordance with this SSP contains the same ingredient (estriol) as Ovestin® cream ○ their dosing schedule remains the same, and they will receive the same amount of estriol per applicator dose with estriol 0.01% cream as they were receiving with Ovestin® 1mg cream. For example, if patients are currently using Ovestin® cream twice a week, they should use estriol 0.01% cream twice a week as directed. See **Annex A** for further information on the two products. ○ clinical experts in menopause have been consulted in the production of this SSP and have advised on this approach. • Ensure patients are aware estriol 0.01% cream is not to be used if the patient is allergic to soya or peanuts. • 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: ○ Vaginal 'breakthrough bleeding' ○ Excessive bloating ○ Further information can be found here (NICE guidance). • Patients who experience persistent side effects from the alternative medicine supplied in accordance with this SSP should be promptly referred back to their prescriber. • 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 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/carer declines to receive medicine under this SSP then they should be referred back to their prescriber promptly.

Valid from:	25 July 2022
Expiry date:	29 October 2022
Reference number:	SSP025
Version number:	1.1

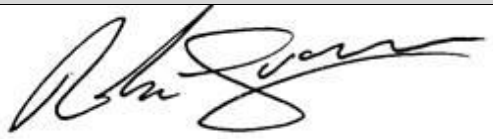
Any queries regarding the content of this SSP which was issued by the Department of Health – Northern Ireland should forwarded to communitypharmacy@health-ni.gov.uk

Change history

Version number	Change details	Date
V1.1	Expiry date extended to 29 October 2022	25/07/2022

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:			
Name	**Position**	**Signature**	**Date**
Minister Robin Swann	DOH Minister		25/07/2022

Annex A - **Dose conversion of estriol (Ovestin® 1mg) 0.1% cream to estriol 0.01% cream**

	Ovestin® 1mg cream	**Estriol 0.01% cream**
Active ingredient	Estriol	Estriol
Strength	0.1% (1mg per 1g)	0.01% (100micrograms per 1g)
Applicator dose	1 applicator dose (0.5g of cream) = 0.5mg estriol	1 applicator dose (5g of cream) = 0.5mg estriol
Dose	1 application per day for the first weeks (maximally 4 weeks), followed by a gradual reduction, based on relief of symptoms, until a maintenance dosage (e.g., 1 application twice a week) is reached as directed.	1 application per day initially followed by a dose of 1 application twice a week for maintenance as directed after restoration of the vaginal mucosa has been achieved.