

SERIOUS SHORTAGE PROTOCOL (SSP)

Reference Number: SSP035

This SSP applies to the following medicine:

Name of medicine (including strength and formulation)	Estraderm MX® 25 microgram patch. <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>
Legal category	POM

1. Details of medication to be supplied under this SSP

Name of medicine (including formulation and strength) to be supplied	Evorel® 25 microgram patch
Quantity of this formulation (if applicable)	Total quantity supplied under this protocol to be equivalent to the number of days supplied on the original prescription. For every Estraderm MX® 25 microgram patch, the following quantity must be supplied in accordance with this protocol: 1 x Evorel® 25 microgram patch
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
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Clinical situation to which this Serious Shortage Protocol (SSP) applies

Scope of SSP	All NHS and private prescriptions. This protocol does not allow for the quantity supplied to be less than the number of days prescribed on original prescription.
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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 Estraderm MX® 25 microgram patches • 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 Estraderm MX® 25 microgram patches. • The patient presents a prescription that 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 Evorel® 25 microgram patches or their excipients. • Patients aged less than 18 years.
Cautions including any relevant action to be taken	<ul style="list-style-type: none"> • Ensure that patients considered unsuitable for inclusion are promptly referred to their prescriber for further advice. • Ensure that the patient's prescriber and/or GP practice is notified when supplying a patient in accordance with this SSP. • 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'; ○ Irritation caused by wearing a different patch to one they are used to; ○ Patches coming off or not adhering properly. • Patients who experience persistent side effects from alternative patches supplied in accordance with this SSP should be promptly referred back to their prescriber.
Special considerations for specific populations of patients	<p>Switching the presentation (including different manufacturer) of the drug requires caution in certain patients who are considered at risk of deterioration due to the nocebo effect whereby patients believe that the exact presentation (including different manufacturer) of the drug is critical to their response.</p> <p>Patients considered at higher risk of experiencing the nocebo effect need to be referred back to their prescriber promptly for further advice</p>
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:	8 September 2022
Expiry date:	16 September 2022
Reference number:	SSP035
Version number:	1.0


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

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		15/9/22