**SERIOUS SHORTAGE PROTOCOL (SSP)**

**Reference Number:** SSP035

This SSP applies to the following medicine:

<table>
<thead>
<tr>
<th>Name of medicine (including strength and formulation)</th>
<th>Estraderm MX® 25 microgram patch</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pharmacists must ensure that the patient’s prescriber and/or GP practice is notified within 24 hours when supplying a patient in accordance with this SSP.</strong></td>
<td></td>
</tr>
</tbody>
</table>

| Legal category | POM |

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

<table>
<thead>
<tr>
<th>Name of medicine (including formulation and strength) to be supplied</th>
<th>Evorel® 25 microgram patch</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Quantity of this formulation (if applicable)</strong></td>
<td>Total quantity supplied under this protocol to be equivalent to the number of days supplied on the original prescription.</td>
</tr>
<tr>
<td></td>
<td>For every Estraderm MX® 25 microgram patch, the following quantity must be supplied in accordance with this protocol:</td>
</tr>
<tr>
<td></td>
<td>1 x Evorel® 25 microgram patch</td>
</tr>
<tr>
<td><strong>Substitution results in a change to whether the use is licenced</strong></td>
<td>No</td>
</tr>
</tbody>
</table>
Scope for which this Serious Shortage Protocol (SSP) applies

| The SSP applies to the following parts of the UK | UK-wide |

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. |
| Criteria for inclusion | • 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 | • The patient presents with a prescription for a medicine other than Estraderm MX® 25 microgram patches.  
• 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 Evorel® 25 microgram patches or their excipients.  
• Patients aged less than 18 years. |
| Cautions including any relevant action to be taken | • 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:
  o Vaginal 'breakthrough bleeding';
  o Irritation caused by wearing a different patch to one they are used to;
  o 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
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.

Patients considered at higher risk of experiencing the nocebo effect need to be referred back to their prescriber promptly 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: 08/09/2022
Expiry date: 16/09/2022
Reference number: SSP 035
Version number: 1.0

Any queries regarding the content of this SSP which was issued by the Secretary of State for Health and Social Care, should be addressed to NHS Prescription Services.

You can get in contact by:
Email: nhsbsa.prescriptionservices@nhsbsa.nhs.uk
Telephone: 0300 330 1349
Textphone: 18001 0300 330 1349

You can also write to us at:
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 https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors-serious-shortage-protocols-ssps.
- Users must not alter, amend or add to the content of this document; such action will invalidate the SSP.

Ministerial ratification by:

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lord Syed Kamall</td>
<td>PUSS for Technology Innovation and Life Sciences</td>
<td>[Signature]</td>
<td>08/09/2022</td>
</tr>
</tbody>
</table>
ADDENDUM
Supporting information on notifying other healthcare professionals

- Any items supplied in accordance with an SSP in response to an NHS prescription also needs to be supplied in accordance with NHS Pharmaceutical and Local Pharmaceutical Services Regulations.

- Those Regulations provide that where a therapeutic equivalent is supplied, a pharmacist will need to inform a patient’s GP practice. This would generally be expected within the next working day, but further guidance would be given in any case where this applied.

- Where a different quantity, an alternative pharmaceutical form, an alternative strength or a generic equivalent is provided, it may not always be necessary that the patient’s prescriber is informed, as the existence of the SSP may be enough for the prescriber to be aware that these changes in dispensing may take place, unless national arrangements agreed with the relevant representative bodies state otherwise. However, guidance may be issued on particular SSPs to indicate that prescribers should be informed of any patients that receive supply under it.

- In the absence of any preferred local alternate communication channels, all feedback to prescribers should be sent by NHSmail. The NHS Service Finder is a way for pharmacies to look up the email address of the patient’s GP.