

# SERIOUS SHORTAGE PROTOCOL (SSP)

Reference Number: SSP012

This SSP applies to the following medicine:

<b>Name of medicine (including strength and formulation)</b>	Estradot <sup>®</sup> 75 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.</u>
<b>Legal category</b>	POM

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

<b>Name of medicine (including formulation and strength) to be supplied</b>	Evorel <sup>®</sup> 75 microgram patch  OR  Estraderm MX <sup>®</sup> 75 microgram patch
<b>Quantity of this formulation (if applicable)</b>	Total quantity supplied under this protocol to be equivalent to the number of days supplied on original prescription.  For every Estradot <sup>®</sup> 75 microgram patch, the following quantity must be supplied in accordance with this protocol:  1 x Evorel <sup>®</sup> 75 microgram patch  OR  1 x Estraderm MX <sup>®</sup> 75 microgram patch
<b>Substitution results in a change to whether the use is licenced</b>	No

## Scope for which this Serious Shortage Protocol (SSP) applies

<b>The SSP applies to the following parts of the UK</b>	England and Wales
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## Clinical situation to which this Serious Shortage Protocol (SSP) applies

<b>Scope of SSP</b>	All NHS and private prescriptions. This protocol does <b>not</b> allow for the quantity supplied to be less than the number of days prescribed on original prescription.
<b>Criteria for inclusion</b>	<ul style="list-style-type: none"> <li>• The patient presents with a valid prescription (meeting the requirements of the Human Medicines Regulations 2012) for Estradot® 75 microgram patches</li> <li>• The patient/carer consents to receiving the medicine supplied under this SSP.</li> <li>• All patients aged 18 years of age or above.</li> </ul>
<b>Criteria for exclusion</b>	<ul style="list-style-type: none"> <li>• The patient presents with a prescription for a medicine other than Estradot® 75 microgram patches.</li> <li>• The patient presents a prescription which is not valid.</li> <li>• The patient/carer does not consent to receiving the medicine(s) supplied under this SSP.</li> <li>• Where the pharmacist, using their professional judgement, determines that the patient is not suitable to receive alternative medicine under this SSP.</li> <li>• Known previous hypersensitivity or severe adverse reaction to Evorel® 75 microgram patches or Estraderm MX® 75 microgram patches or their excipients.</li> <li>• Patients aged less than 18 years.</li> <li>• Adults on an Estradot® dose &gt; 150micrograms per week.</li> </ul>
<b>Cautions including any relevant action to be taken</b>	<ul style="list-style-type: none"> <li>• Ensure that patients considered unsuitable for inclusion are promptly referred to their prescriber for further advice.</li> <li>• Ensure that the patient's prescriber and/or GP practice is notified when supplying a patient in accordance with this SSP.</li> <li>• Ensure that patients who are supplied in accordance with this SSP are counselled by the pharmacist with</li> </ul>

	<p>regards to monitoring and managing potential side effects, such as:</p> <ul style="list-style-type: none"> <li>○ Vaginal ‘breakthrough bleeding’;</li> <li>○ Irritation caused by wearing a different patch to one they are used to;</li> <li>○ Patches coming off or not adhering properly.</li> </ul> <ul style="list-style-type: none"> <li>● Patients who experience persistent side effects from alternative patches supplied in accordance with this SSP should be promptly referred back to their prescriber.</li> </ul>
<b>Special considerations for specific populations of patients</b>	<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 <b>nocebo</b> 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>
<b>Action to be taken if the patient is excluded</b>	If a patient does not meet the criteria within this SSP then they should be referred back to their prescriber promptly.
<b>Action to be taken if the patient or carer declines the supply</b>	If a patient/carer declines to receive medicine under this SSP then they should be referred back to their prescriber promptly.

<b>Valid from:</b>	29 April 2021
<b>Expiry date:</b>	4 June 2021
<b>Reference number:</b>	SSP012
<b>Version number:</b>	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](mailto:nhsbsa.prescriptionservices@nhsbsa.nhs.uk)

**Telephone:** 0300 330 1349

**Textphone:** 18001 0300 330 1349

You can also write to us at:


Newcastle	Middlebrook	Wakefield
NHS Prescription Services Bridge House 152 Pilgrim Street Newcastle upon Tyne NE1 6SN	NHS Prescription Services Ridgway House Northgate Close Middlebrook Horwich Bolton BL6 6PQ	NHS Prescription Services 4th Floor Wakefield House Borough Road Wakefield WF1 3UB

## 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 <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:			
Name	Position	Signature	Date
Lord Bethell	Minister for Innovation, DHSC		29.04.2021

## **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.