Department of Health & Social Care

NHS

UPDATE:

Update to communication issued 3 May 2022

Medicine Supply Notification

MSN/2022/037-U

Estradiol (Oestrogel® Pump-Pack 750microgram per actuation) 0.06% gel

Tier 2 – medium impact*
Date of issue: 23/05/2022
Link: Medicines Supply Tool

Summary

- Estradiol (Oestrogel® Pump-Pack 750microgram per actuation) 0.06% gel is experiencing intermittent supply issues with a resolution date to be confirmed.
- A Serious Shortage Protocol (SSP) was issued on 29/04/2022 which allowed community pharmacists to limit supply to three months.
- Two additional SSP's were issued on 20/05/2022 allowing community pharmacists to supply estradiol patches which remain available, if estradiol (Oestrogel® Pump-Pack 750microgram per actuation) 0.06% gel is unavailable.
- Where this is not appropriate, alternative hormone replacement therapies also remain available.
- Where the above alternatives are not suitable, unlicensed supplies can be sourced, lead times vary.

Actions Required

Where supplies of estradiol (Oestrogel® Pump-Pack) 0.06% gel **are available**, community pharmacists should consider;

- limiting supply to three months of supply in accordance with SSP 019 for eligible patients presenting with a prescription for more than three months' supply of estradiol (Oestrogel® Pump-Pack) 0.06% gel (see supporting information).

Where supplies of estradiol (Oestrogel® Pump-Pack) 0.06% gel **are not available**, pharmacists should consider;

- offering a near equivalent strength of estradiol patch (see Table 1), taking into account the patient's current daily dose of estradiol, in accordance with SSP 022 for eligible patients presenting with a prescription for supply of three months or less of estradiol (Oestrogel® Pump-Pack) 0.06% gel (see supporting information); or
- offering a near equivalent strength of estradiol patch (see Table 1), taking into account the patient's current daily dose of estradiol, and limiting supply to three months of supply in accordance with SSP 023 for eligible patients presenting with a prescription for supply of more than three months' supply of estradiol (Oestrogel® Pump-Pack) 0.06% gel (see supporting information).

If the patient is deemed ineligible or does not consent to receive an alternative product via the SSP, clinicians should review and consider prescribing the below, taking into account the patient's treatment indication:

- a maximum of three months' supply of an alternative hormone replacement therapy liaising with local pharmacy teams to identify which products are currently available; or

*Classification of Tiers can be found at the following link:
https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/

- unlicensed products only where licensed alternatives are not appropriate. Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see supporting information).

Supporting information

Clinical information

Switching to estradiol patches:

- If a patient has been referred from the community pharmacy to the prescriber as they are unable to utilise the SSP to switch to an appropriate strength of estradiol patch, clinicians should investigate the reasons behind this with the patient.
- If referral has been made by the community pharmacist as the patient has reported previous adverse reactions to estradiol patches, consider whether an alternative brand of patch would be suitable, see Table 1. If the previous reaction was severe, consider alternative hormone replacement therapy or unlicensed imports.
- Patients may require titration of their dose if symptom control is not achieved within 8 weeks.

Patient counselling points:

- Patients should be made aware of the following and advised to return to the prescriber:
  - for further investigation if they experience persistent side effects including vaginal 'breakthrough bleeding';
  - for consideration of alternative therapies if they are switching to estradiol patches and experience any patch adhesion issues or skin irritation; and
  - for dose titration if they feel the symptoms of menopause have gotten worse 8 weeks after switching to a new product.

- 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 an alternative oestrogen preparation including estradiol patches.

Table 1- Dose equivalence between estradiol (Oestrogel® Pump-Pack) 0.06% gel and estradiol patches*

Current daily dose of estradiol (Oestrogel® pump pack 750mcg/actuation) 0.06% gel	Equivalent dose of estradiol patch	Patch options	Dosing
2 pumps daily	**50 microgram patch**	Progynova TS®	Apply one patch WEEKLY
		FemSeven®	Apply one patch WEEKLY
		Evorel®	Apply one patch **TWICE WEEKLY**
		Estraderm MX®	Apply one patch **TWICE WEEKLY**
3 pumps daily	**75 microgram patch**	FemSeven®	Apply one patch WEEKLY
		Evorel®	Apply one patch **TWICE WEEKLY**
		Estraderm MX®	Apply one patch **TWICE WEEKLY**
4 pumps daily	**100 microgram patch**	FemSeven®	Apply one patch WEEKLY
		Progynova TS®	Apply one patch WEEKLY

		Evorel®	Apply one patch **TWICE WEEKLY**
		Estraderm MX®	Apply one patch **TWICE WEEKLY**

*Note: All patches can only support a partial uplift in demand. The dose equivalents are subject to individual variations in absorption and metabolism.

Please see the link for further information on the SSP's for estradiol (Oestrogel® Pump-Pack) 0.06% gel

Please see links for further advice on alternative hormone replacement therapies:

- CKS Hormone replacement therapy
- British Menopause Society – HRT preparations and equivalent alternatives
- Specialist Pharmacy Service – prescribing available HRT products
- Hormone replacement therapy treatment summary - BNF

Additional information:

- Estraderm MX® SmPC
- Evorel® SmPC
- Femseven® SmPC
- Progynova TS® SmPC
- Oestrogel® pump pack 0.06% gel SmPC

Guidance on ordering and prescribing unlicensed imports

The following specialist importers have confirmed they can source unlicensed oestradiol 0.06% gel (please note there may be other companies that can also source supplies):

- Target Healthcare
- Mawdsley's Unlicensed

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information:

- The supply of unlicensed medicinal products, Medicines and Healthcare products Regulatory Agency (MHRA)
- Professional Guidance for the Procurement and Supply of Specials, Royal Pharmaceutical Society
- Prescribing unlicensed medicines, General Medical Council (GMC),

When prescribing a product that is not licensed in the UK due to a supply issue with the licensed alternative prescribers must indicate on the FP10 prescription that an unlicensed product is required. This can be done in one of the following two ways:

- Electronic prescriptions – if the required unlicensed product is shown on electronic prescribing systems, GPs should select:
    - Gynokadin® 0.06% gel (imported)
    - Oestraclin® 0.06% gel (imported)
- Paper prescriptions – where the unlicensed product is not shown on electronic prescribing systems, GPs should use a paper prescription and annotate with the following wording: "**special order**".

Enquiries

If you have any queries, please contact DHSCmedicinesupplyteam@dhsc.gov.uk.