



UPDATE:

Update to communication issued 3 May 2022

Medicine Supply Notification

MSN/2022/038-U

Estriol (Ovestin® 1mg) 0.1% cream

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

Summary

- Estriol (Ovestin® 1mg) 0.1% cream is experiencing intermittent supply issues until July 2022.
- 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 estriol 0.01% cream which remains available, if estriol (Ovestin® 1mg) 0.1% cream 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 estriol (Ovestin[®] 1mg) 0.1% cream **are available**, community pharmacists should consider;

• limiting supply to three months of supply in accordance with <u>SSP 020</u> for eligible patients presenting with a prescription for more than three months' supply of estriol (Ovestin® 1mg) 0.1% cream (see supporting information).

Where supplies of estriol (Ovestin® 1mg) 0.1% cream **are not available**, community pharmacists should consider;

- offering estriol 0.01% cream with the same dosing instructions (each applicator dose of estriol (Ovestin® 1mg) 0.1% cream and estriol 0.01% cream delivers estriol 0.5mg), in accordance with SSP 024 for eligible patients presenting with a prescription for supply of three months or less of estriol (Ovestin® 1mg) 0.1% cream (see supporting information); or
- offering estriol 0.01% cream with the same dosing instructions (each applicator dose of estriol (Ovestin® 1mg) 0.1% cream and estriol 0.01% cream delivers estriol 0.5mg) and limiting supply to three months of supply in accordance with <u>SSP 025</u> for eligible patients presenting with a prescription for supply of more than three months' supply of estriol (Ovestin® 1mg) 0.1% cream (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

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

Each applicator dose of estriol (Ovestin® 1mg) 0.1% cream and estriol 0.01% cream delivers estriol 0.5mg; it is possible that patients on estriol 0.01% cream may need to be reviewed for effectiveness of treatment after 8 weeks.

NOTE: Estriol 0.01% cream contains peanut oil.

Table 1- comparison of estriol (Ovestin® 1mg) 0.1% cream and estriol 0.01% cream

	Estriol (Ovestin® 1mg) 0.1% 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.	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.

Please see the link for further information on SSP's for estriol (Ovestin® 1mg) 0.1% cream

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

Links to further information:

- Estriol 0.01% cream SmPC
- Ovestin[®] 1mg cream SmPC

Guidance on ordering and prescribing unlicensed imports

The following specialist importer(s) have confirmed they can source unlicensed Ovestin[®] 1mg cream (please note there may be other companies that can also source supplies):

Target Healthcare

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:

- <u>The supply of unlicensed medicinal products</u>, 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:
 - Ovestin[®] 1mg cream (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.