

To:
All GP Practices
All Community Pharmacies

Tel : 028 9536 3375
Fax : 028 9536 1166
Web Site :
www.hscboard.hscni.net

29th August 2019

Dear Colleague,

HORMONE REPLACEMENT THERAPY (HRT) SUPPLY ISSUES

The purpose of this letter is to inform you of the current supply issues affecting some HRT products. These are temporary shortages which pharmaceutical companies and their suppliers are trying to resolve.

HRT availability

Table 1 in the attached Appendix provides the latest update on HRT availability. Further information is also available at:

Specialist Pharmacy Service website:
<https://www.sps.nhs.uk/articles/shortage-of-evorel-hormone-replacement-therapy-hrt-patch-range/>

British Menopause Society website:
<https://thebms.org.uk/2019/08/british-menopause-society-update-on-hrt-supply-shortages/>

Clinicians may be required to switch patients to alternative HRT products and should work closely with community pharmacies to understand the local availability of HRT products.

Advice on switching

There is a wide range of alternative treatment options, subject to availability. The British Menopause Society advises that prescribers consider equivalent preparations that provide a similar dose to what their patient is using. If an exact match is not possible, prescribers can seek

guidance available on the practical prescribing chart on its website and [Menopause Matters website](#), to clarify equivalent doses.

Evorel patches

The entire Evorel patch range will be out of stock from October 2019. Further guidance to advise on suitable alternatives is available at the following link:

<https://www.sps.nhs.uk/articles/shortage-of-evorel-hormone-replacement-therapy-hrt-patch-range/>

For some more complex cases, advice may need to be sought from specialists. If there is insufficient transdermal estradiol products to meet demand then prioritising their use for women at increased risk of VTE may have to be considered.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Joe Brogan', with a stylized flourish at the end.

Joe Brogan
Assistant Director Integrated Care
Head of Pharmacy and Medicines Management

Enc.

Appendix 1: Hormone replacement therapy (HRT) supply issues

- The Department of Health and Social Care (DHSC) are aware of the ongoing manufacturing issues that have affected the supply of some hormone replacement therapy (HRT) products throughout 2019.
- Please see Table 1, which provides the latest update on the availability of all HRT products marketed in the UK and the known resupply date for products that's are currently experiencing supply issues.
- This table also provides an update of all HRT preparations that remain available. Clinicians may be required to switch patients to alternative HRT products that contain the same active ingredients for a temporary period.
- Prescribing information regarding HRT equivalence to support local decision making is available through various sources such as the British National Formulary, Summary of Product Characteristics (SPC), The Monthly Index of Medical Specialities (MIMS), and other sources including local Medicines Information Centres.
- Clinicians are advised to work closely with community pharmacies to understand local availability of HRT products and use the table below to help make decision about appropriate HRT products for patients who are affected by the supply issues.
- DHSC will continue to provide updates on HRT availability in the monthly supply report, which is uploaded to the Specialist Pharmacist Services website. All registered user can access this update via this following link: <https://www.sps.nhs.uk/articles/department-of-health-and-pharmaceutical-market-strategy-group-pmsg-supply-updates/>
- Please share this information with relevant networks locally including GP practices and community pharmacies.

Table 1. HRT Availability

		Oestrogen Only			
Ingredient (s)	Manufacturer	Brand	Strength	Current Availability	Anticipated resupply date
		Oral preparations			
Estradiol hemihydrate	Mylan	Elleste Solo*	1mg	In stock	Continued availability to be confirmed. Please see below the table for more information on the Elleste range *
			2mg	In stock	
	Mylan	Zumenon*	1mg	OOS	Mid-September 2019
			2mg	OOS	End of August 2019
Estradiol valerate	Bayer	Progynova	1mg	In stock	
			2mg	In stock	
Estradiol	Resource Medical UK	Bedol	2mg	Long term OOS	
Transdermal patches					
Estradiol	Janssen-Cilag	Evorel **	25 mcg	In stock until mid to end of February 2020	Mid 2020 please see below the table for more information on the Evorel range**.
			50mcg	In stock until end of October 2019	

			75mcg	In stock until beginning of October 2019	
			100mcg	In stock until beginning of October 2019	
Estradiol hemihydrate	Novartis	Estradot	25 mcg	In stock	
			37.5mcg	In stock	
			50mcg	In stock	
			75mcg	In stock	
			100mcg	In stock	
	Merus Labs/Norgine	Estraderm	25 mcg	In stock	
			50mcg	In stock	
			75mcg	In stock	
			100mcg	In stock	
	Theramex	FemSeven Mono	50mcg	In stock	
			75mcg	In stock	
			100mcg	In stock	
Bayer	Progynova TS	50mcg	In stock		
		100mcg	In stock		
Mylan	Elleste Solo MX *	40mcg	In stock	Continued availability to be confirmed	
		80mcg	In stock		
Conjugated oestrogen	Pfizer	Premarin	300mcg	In stock	
			625mcg	In stock	
			1.25mcg	In stock	
Topical (Transdermal gels/creams/other delivery systems)					
Estradiol	Besins Healthcare (UK) Ltd	Oestrogel	0.06%	In stock	
Estradiol hemihydrate	Orion	Sandrena	0.5mg	In stock	
			1mg	In stock	
	Pfizer	Estring vaginal delivery system	7.5mcg/24hours	In stock	
	Novo Nordisk	Vagifem vaginal tablets	10mcg	In stock	
estriol	Flynn Pharma	Blissel	50mcg/g	In stock	
	Marlborough Pharma	Estriol cream (generic)	0.01%	In stock	
	Aspen	Ovestin cream	1mg	In stock	
Progestogen only					
Medroxyprogesterone	Resource Medical UK	Climanor	5mg	long term OOS	
Levonorgestrel	Bayer	Mirena Intrauterine device	20mcg/24hrs	In stock	

Progesterone	Besins Healthcare (UK) Ltd	Utrogestan	100mg	In stock	
		Utrogestan	200mg	In stock	
Combined HRTs (Progestogen and oestrogen)					
Continuous combined therapy					
Oral preparations					
Estradiol hemihydrate / norethisterone acetate	Mylan	Elleste Duet Conti*	2mg / 1mg	In stock at wholesalers	Continued availability to be confirmed
		Novo Nordisk	Kliofem	2mg/ 1mg	In stock
	Kliovance		1mg/ 500mcg	In stock	
Estradiol hemihydrate / dydrogesterone	Mylan	Femoston Conti	500mcg/ 2.5mg	In stock	
			1mg/ 5mg	In stock	
Estradiol valerate/medroxyprogesterone	Orion	Indivina	1mg /2.5mg	In stock	
			2mg/ 5mg	OOS	End of August 2019.
			1mg/5mg	In stock	
low dose conjugated oestrogen/medroxyprogesterone	Pfizer	Premique	300mcg/1.5mg	In stock	
Transdermal patch					
Estradiol hemihydrate/ norethisterone acetate	Janssen-Cilag	Evorel Conti **	3.2mg/11.2mg	In stock - mid to end of October 2019	Mid 2020 See below **
Estradiol hemihydrate/ levonorgestrel	Theramex	FemSeven Conti	1.5mg/ 0.525mg	Long term OOS	Q2 2020
Sequential combined therapy					
Oral preparations					
Estradiol [X,X] / norethisterone acetate	Resource Medical UK	Clinorette	[2mg, 2mg]/ 1mg	Long term OOS	
Estradiol/norgestrel	Mylan	Cycloprogynova	2mg/500mcg	Long term OOS	
Estradiol hemihydrate / norethisterone acetate		Elleste Duet *	1mg/ 1mg	In stock	Continued availability to be confirmed
			2mg/ 1mg	In stock	
Estradiol hemihydrate/ dydrogesterone		Femoston	1mg/ 10mg	limited stock	
			2mg/10mg	In stock	
Estradiol hemihydrate / norethisterone acetate	Novo Nordisk	Novofem	1mg/ 1mg	In stock	
Estradiol valerate/ medroxyprogesterone acetate		Tridestra	2mg/20mg	In stock	
Estradiol hemihydrate [X,X,X]/ norethisterone acetate	Orion	Trisequens	[2mg, 2mg, 1mg]/ 1mg	In stock	
Transdermal patch					
a) Estradiol hemihydrate and b) estradiol hemihydrate/ norethisterone acetate	Janssen-Cilag	Evorel Sequi**	a)3.2mg b) 3.2 mg /11.2 mg	In stock until mid-September 2019	Mid 2020 See below **
a) 1.5mg of estradiol hemihydrate b) Estradiol hemihydrate /levonorgestrel	Theramex	FemSeven Sequi	a) 1.5mg b) 1.5mg /1.5mg	Long term OOS	Q2 2020

Gonadomimetic (s)					
Tibolone 2.5mg	Advanz Pharma	Livial tablets	Tibolone 2.5mg	In stock	
Selective oestrogen receptor modulator					
Ospemifene 60mg tablets	Shionogi	Senshio tablets	Ospemifene 60mg tablets	In stock	
Tissue-selective oestrogen complex					
Conjugated oestrogen 300mcg/ bazedoxifene 20mg	Pfizer	Duavive	conjugated oestrogen 300mcg/ bazedoxifene 20mg	In stock	

*Elleste HRT Range:

- Mylan have recently advised that supplies of all the Elleste Range (Elleste Duet Conti, Elleste Duet 2mg tablets, Elleste solo 1mg and 2mg tablets, Elleste Duet 1mg and 2mg and Elleste MX 40 and 80micrograms patches) have been replenished and are now available.
- However, Mylan have advised they are still experiencing on going manufacturing problems, therefore, currently they do not have visibility on future supplies.
- DHSC are working with Mylan and awaiting further information to understand the long-term implications of this.

**Evorel HRT transdermal patch range:

- Janssen-Cilag, the manufacturer of the Evorel HRT transdermal patch range (Evorel; Evorel Conti; Evorel Sequi) have notified the DHSC that due to manufacturing constrictions, the whole range will be out of stock from October 2019 for most presentations and others are expected to last until early 2020. Current forecasted stock out dates for specific Evorel products are listed in Table 1.
- Currently, Janssen-Cilag are unable to give an exact resupply date beyond mid-2020.
- UK Medicine Information have published guidance to advise on suitable alternatives. This provides a range of alternative options and highlights the need for prescribers to seek specialist advice for more complex patients and consider prioritising the use of transdermal HRT therapy for women at increased risk of venous thrombosis <https://www.sps.nhs.uk/articles/shortage-of-evorel-hormone-replacement-therapy-hrt-patch-range/>