



Llywodraeth Cymru
Welsh Government

MEDICINES SHORTAGE ADVISORY GROUP WALES

MEDICINE SHORTAGE

Distribution:	As Annex 1
From:	Andrew Evans, Chief Pharmaceutical Officer
Date:	04 September 2019
Reference:	CPhO/MedsLet/2019/12
Category:	Level 3 - High impact
Title:	Disruption to supply of Evorel® Hormone Replacement Therapies (HRT)
For Action by:	<ul style="list-style-type: none">• All General Practitioners - retain a copy in your 'locum information pack'. Action as below.• Dispensing General Practitioners – please ensure this message is seen by all working in your dispensary and retain a copy in your 'locum information pack'. Action as below.• Community Pharmacists - Action as below.• Hospital Chief Pharmacists - Action as below.• Medical Directors of Health Boards - disseminate to relevant clinicians in secondary care setting – Action as below.
Timeframe:	Action within 24 hrs
For Information:	See Annex 1 – Distribution List
Key Recipients:	Chief Executives of Health Boards Nurse Directors Health Boards

Directors of Public Health
Health Board and NHS Trust Chief Pharmacists
Health Board Prescribing Advisers
Chief Executives of NHS Trusts
Director Welsh Medicines Information Centre
NHS Direct Wales

What is this about:

Disruption to the supply of Evorel® Hormone Replacement Therapies (HRT) manufactured by Janssen-Cilag.

Description of product affected:

- Evorel Conti® (estradiol 50 micrograms and norethisterone 170micrograms /24 hours) transdermal patches
- Evorel Sequi® (Evorel Conti + Evorel 50 microgram patches) transdermal patches
- Evorel® (estradiol only) 25, 50.75, 100 patches

Issue & Action to be taken:

ISSUE

Disruption to the supply of Evorel® Hormone Replacement Therapies (HRT) expected to continue until mid - 2020.

Janssen-Cilag report to have 60% - 70% of the market share across the transdermal patch range for HRTs. They are also the sole suppliers for the combined HRT patches, Evorel Conti® and Sequi®.

Current forecasted stock out dates for specific Evorel products are listed in Table 1.

Indications

Evorel Conti ®

Used in oestrogen deficiency symptoms in post-menopausal women more than 6 months post-menopause (or 18 months since last period).

Evorel® 25, 50.75, 100 patches and Evorel Sequi ®

Used for oestrogen deficiency symptoms in peri- and post-menopausal women.

All Evorel® preparations (with the exception of Evorel 25)®

Used for prevention of osteoporosis in post-menopausal women at high risk of future fractures who are intolerant of, or contra-indicated for, other medicinal products approved for the prevention of osteoporosis.

Availability

The below table provides the latest information on the availability of all HRT products marketed in the UK and the known resupply date for products that are currently experiencing supply issues. It also indicates all HRT preparations that remain available.

		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	Cycloprogy nova	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 Se qui	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	

ACTION:

Clinicians may be required to switch patients to alternative HRT products that contain the same active ingredients for a temporary period.

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.

GUIDANCE:

UK Medicine Information (UKMI) 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/>

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 the Welsh Medicines Information Centre.

QUERIES

For all correspondence please contact:

Medicinesshortages@gov.wales

Please forward to listed recipients.

Yours sincerely

A handwritten signature in black ink that reads "Andrew Evans". The signature is written in a cursive style with a large initial 'A' and 'E'.

Andrew Evans

Chief Pharmaceutical Officer/Prif Swyddog Fferyllo
Welsh Government/Llywodraeth Cymru

DISTRIBUTION LIST

Send to:

Chief Executives of Health Boards
Medical Directors of Health Boards
Health Board Chief Pharmacists
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Chief Executives of NHS Trusts
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