

## Supply Issues Update for Primary and Secondary Care: September 2019

This report has been produced by the Department of Health and Social Care (DHSC) Medicine Supply Team. We aim to update this report monthly to provide an update on current primary and secondary care medicine supply issues that we are working on. This information is confidential to the NHS; please do not upload to websites in the public domain. Please do share with relevant colleagues and networks.

Where it has been stated 'a clinical memo from UKMI will be published on the SPS website', this will be found at the following URL: <https://www.sps.nhs.uk/category/shortages-discontinuations-and-expiries/>

### Contents

New Issues .....	3	Acetylcholine Chloride (Miochol-E) 20mg powder and solvent for irrigation .....	8
Injectables .....	3	Aciclovir 500mg/1g injection .....	8
Diamorphine 5mg injection .....	3	Amikacin 500mg/2ml injection .....	8
Adrenaline 1 in 1000, 1ml ampoules .....	4	Emerade 500 microgram and 300 microgram adrenaline auto-injector (AAI) devices .....	8
Lanoxin (digoxin) 250mcg/ml injection .....	4	EpiPen and EpiPen Junior .....	9
Sayana Press (medroxyprogesterone acetate 104mg) injection .....	5	Erwinase injection .....	9
Orals .....	5	Haloperidol 5mg/ml injection .....	9
Accuretic (quinapril 10mg/hydrochlorothiazide 12.5mg) tablets ..	5	Idarubicin 10mg injection (Zavedos) .....	9
Brevinor (norethisterone 500micrograms and ethinylestradiol 35 micrograms) tablets .....	5	Labetalol 5mg/mL injection .....	9
Fluoxetine 10mg/30mg/40mg capsules .....	5	Neurobloc (Botulinum Toxin Type B) .....	10
Galantamine 8mg/12mg tablets .....	5	Oncaspar (pegaspargase) 750 U/ml solution for injection/infusion .....	10
Hypovase (prazosin) 1mg tablets .....	6	Tetracosactide 1mg depot injection .....	10
Megace (megestrol) 160mg tablets .....	6	Tobramycin 240mg/6ml injection .....	10
Mianserin 10mg/30mg tablets .....	6	Urokinase injection .....	10
Nardil (phenelzine sulfate ) 15mg tablets .....	7	Orals .....	11
Zidovudine 250mg capsules .....	7	Actiq (fentanyl) lozenges .....	11
Others .....	7	Adalat (nifedipine) tablets/capsules .....	11
Capsaicin (Zacin) 0.025%/(Axsain) 0.075% cream .....	7	Bumetanide 5mg tablets .....	11
Efudix (fluorouracil) 5% cream .....	7	Carbagen (carbamazepine) various preparations .....	11
Flamazine (silver sulfadiazine) 1% cream .....	8	Cefuroxime 125mg/5ml suspension (Zinnat) .....	12
Ongoing Issues .....	8	Colestid (colestipol) 5g granules .....	12
Injectables .....	8	Disopyramide 150mg capsules .....	12

COMMERCIAL-SENSITIVE	
Epanutin (phenytoin) 50mg Chewable	Hepatitis B Vaccines..... 19
Infatabs.....12	Menveo..... 19
Heminevrin (clomethiazole) 192mg capsules	Rabipur (Rabies vaccine)..... 19
.....12	Discontinuations..... 20
Hormone Replacement Therapy products	Adasuve (loxapine) 9.1mg inhalation powder
(HRT).....12	(Ferrer)..... 20
Metoprolol 50mg and 100mg tablets.....14	Ammonaps (sodium phenylbutyrate)
Olena (fluoxetine) 20mg dispersible tablets14	940mg/g granules (SOBI)..... 20
Oral Contraceptive Pill products (OCP) .....14	Bovine Insulin (Wockhardt) ..... 20
<i>Norimin (ethinylestradiol/norethisterone)</i>	Cilest (norgestimate 250mcg and
<i>0.035mg/1mg tablets</i> .....14	ethinylestradiol 35mcg) tablets (Janssen-
Physeptone (methadone) 5mg tablets.....15	Cilag) ..... 20
Questran Powder for Oral Suspension .....15	Dexamfetamine 1mg/1ml oral solution
Quinapril 5mg/10mg tablets .....15	(Ethypharm)..... 20
Sinemet 10/100mg tablets .....15	Isotrexin Gel (isotretinoin and erythromycin)
Stemetil (prochlorperazine) 5mg in 5ml oral	(Stiefel)..... 21
syrup .....16	Modecate (fluphenazine decanoate) injection
Tiagabine tablets .....16	..... 21
Trifluoperazine tablets .....16	Sebivo (telbivudine) 600mg film-coated
Tuberculosis medications .....16	tablets (Novartis) ..... 21
Others.....17	Stayveer (bosentan) tablets (Janssen-Cilag)21
Dalacin (clindamycin) 2% vaginal cream .....17	Tilade (nedocromil sodium 2mg/dose) Inhaler
Indocid (indometacin) 100mg suppositories	..... 21
.....17	Resolved (date resolved) ..... 22
Instanyl (fentanyl) nasal spray.....17	Actiq (fentanyl) 600mcg lozenges (5/9/19) 22
Nitrous Oxide and Entonox.....18	BOC Medical Carbon Dioxide (29/8/19) ..... 22
Skinoren (azelaic acid) 20% cream .....18	Buflol (bupivacaine 1mg/ml and fentanyl 2
Zentiva: distribution issues.....18	micrograms/ml) solution for infusion 250ml
Eye drops/treatments .....18	(6/9/19)..... 22
Lacri-Lube .....18	Cardura XL (doxazosin) 4mg/8mg tablets
Lotemax .....18	(27/8/19)..... 22
Phenylephrine 10% Minims.....19	Disopyramide 100mg capsules (22/8/19)... 22
Chloramphenicol 0.5% eye drops.....19	Epanutin (phenytoin) 30mg/5ml oral
Betamethasone Ointment 0.1% .....19	suspension (9/9/19)..... 22
Betnesol (betamethasone 0.1%)	Fludarabine 50mg/2ml injection (16/8/19) 22
eye/ear/nose drops .....19	Gadovist preparations 02/08/2019 ..... 22
Vaccines.....19	Joyrides (hyoscine hydrobromide 150
	microgram) tablets (20/8/19)..... 22

COMMERCIAL-SENSITIVE

Ketalar 200mg in 20ml (ketamine hydrochloride 10mg/ml) injection (16/8/19) .....22

Mivacron (mivacurium chloride) injection (5/9/19).....22

Ovranette (ethinylestradiol 30 mcg/levonorgestrel 150mcg) tablets (4/9/19) .....22

Phenylephrine 1mg in 10ml (0.1mg /ml) injection (2/9/19) .....22

Prostin E2 (dinoprostone) 3mg Vaginal Tablet (10/9/19)..... 22

Rifadin (rifampicin) 300mg capsules (27/8/19)..... 22

Sanofi: distribution issues (26/8/19) ..... 22

Appendix..... 22

**Information provided w/c 9th September 2019**

New Issues

Injectables

Diamorphine 5mg injection

- DHSC and NHSE have been notified by Accord and Wockhardt that they are experiencing issues with the manufacture and availability of diamorphine 5mg injection which will not resolve until early October 2019.
- After consulting with all key stakeholders and the national Medicine Shortages Response Group (MSRG), we have developed the following management plan below, which differs for primary and secondary care.
- For any concerns around patient safety, please contact your local Medication Safety Officer who will escalate to Nicola Wake (Medication Safety Lead, Specialist Pharmacy Service).

**Diamorphine Injection (other strengths)**

- There are sufficient stocks of all other strengths of diamorphine injection to support forecasted demand of these strengths in the UK but insufficient stocks to cover the forecasted demand of 5mg strength in both primary and secondary care.

**Alternative Opioids**

- When we experienced a similar supply issue in May 2019 the NHS used morphine 10mg injection as an alternative opioid.
- We have worked with morphine license holders and **Hameln** have sufficient **morphine 10mg injection (preservative free)** to cover the diamorphine shortfall over this period. Martindale CANNOT support increased demand of morphine 10mg injection.
- We have contacted other opioid license holders and the following products are available to support this supply issue in limited quantities. If after talking to your clinical teams you wish to use one of these agents, please discuss your requirements with your regional procurement lead who will check with the suppliers about current availability.

Product	Suppliers	Comment
---------	-----------	---------

COMMERCIAL-SENSITIVE

Morphine Sulphate 10mg (preservative free) injection	Hameln	Consider first line
Remifentanil injection	Aspen, Braun, Wockhardt	Only use following discussion with regional procurement lead
Alfentanil injection	Hameln	Only use following discussion with regional procurement lead
Oxycodone injection	Hameln, Kent, Chanelle, Qdem, Wockhardt	Only use following discussion with regional procurement lead

The updated UKMI memo circulated in May 2019 can be found by following this link –

<https://www.sps.nhs.uk/articles/shortage-of-diamorphine-5mg/>

**Management plan:**

**Primary care, private hospitals, hospices and substance misuse treatment centres**

- There is sufficient diamorphine 5mg injection to support forecasted use. Diamorphine will be available to order from usual wholesalers.

**Secondary care NHS trusts in UK**

- There will be no diamorphine 5mg injection available until early October 2019.
- There is insufficient diamorphine 10mg injection to support secondary care use of diamorphine 5mg injection. Any overordering of the 10mg injection will lead to this presentation going out of stock.
- Hameln's Morphine 10mg injection (preservative free) should be considered first line alternative and is available to order direct from Hameln.
- Continue to order morphine 10mg injection from Martindale in line with historic demand. Martindale **CANNOT** support increased orders.
- Other opioids are available to support this supply issue (see table above) but should only be used following approval by regional procurement lead.
- In order to protect diamorphine 10mg injection volumes we are restricting secondary care trust ordering to Mawdsley's and allocations will be put in place. These allocations are based on historical demand and have been shared with Trust regional leads.
- Weekly orders should be placed with Mawdsley's in line with this allocation. Orders will be monitored throughout the supply issue period - over-ordering will be identified and challenged.
- Orders from Secondary Care Trusts to all other Wholesalers for any presentation of diamorphine injection will be blocked.
- **Please let your regional procurement specialist know of any local issues or if you are considering using an alternative other than morphine.**
- Please cascade onto any relevant networks, who may find this information useful.
- If your trust supports any local hospices with diamorphine injection, please discuss with your regional procurement lead who will review your allocation.

**Adrenaline 1 in 1000, 1ml ampoules**

- DHSC have been notified of a short-term supply issue from all three UK suppliers of adrenaline 1 in 1000, 1ml ampoules.
- Further supplies will be available on 13<sup>th</sup> September.

**Lanoxin (digoxin) 250mcg/ml injection**

- Aspen is the sole supplier of **digoxin** 250mcg/ml injection.

#### COMMERCIAL-SENSITIVE

- There is currently limited supply of the above preparation, which is due to go out of stock at the end of September with a resupply date at the end of November 2019.
- Unlicensed imports are available; lead times may vary. Trust should review local stock holding in light of the supply situation and consider placing orders with importers.
- UKMI have produced a clinical memo on alternative treatments available at the following link:  
<https://www.sps.nhs.uk/articles/shortgae-of-lanoxin-digoxin-250-micrograms-ml-injection/>

#### Sayana Press (medroxyprogesterone acetate 104mg) injection

- Pfizer are out of stock of Sayana Press injection until at least the end of 2019 due to manufacturing delays.
- Depo-Provera (medroxyprogesterone acetate 150mg) is currently available and able to support the market during this time, should clinicians deem a switch appropriate.
- Please see the attached letter from Pfizer for further information.

## Orals

#### Accuretic (quinapril 10mg/hydrochlorothiazide 12.5mg) tablets

- Pfizer currently have limited supply of the above preparation and are due to go out of stock by mid-September with a resupply date of end of November 2019.
- There are several alternative combination preparations of ACE-Inhibitors with diuretics. UKMI have advised that patients can be safely switched, with clinical supervision.

#### Brevinor (norethisterone 500micrograms and ethinylestradiol 35 micrograms) tablets

- Pfizer are out of stock of Brevinor tablets until the end of October 2019.
- No bioequivalent oral contraceptive tablets are currently available.
- Alternative oral contraceptive tablets remain in stock, should clinicians deem a switch appropriate (see OCP section below for further information).

#### Fluoxetine 10mg/30mg/40mg capsules

- Morningside, supplier of fluoxetine 10mg capsules are out of stock until October 25<sup>th</sup>, 2019.
- Advanz, also supply fluoxetine 10mg capsules and are out of stock until the end of November.
- Fluoxetine 10mg tablets remain available from Endo Ventures.
- Advanz, sole supplier of fluoxetine 30mg and 40mg capsules are out of stock of both strengths until end of October 2019.
- Fluoxetine 20mg capsules and fluoxetine 20mg/5ml oral solution remain available.
- See below for information on fluoxetine 20mg dispersible tablets.

#### Galantamine 8mg/12mg tablets

- Teva will be out of stock of their immediate release galantamine preparations (8mg and 12mg) until 2020.
- We have been advised that galantamine modified release preparations are readily available (8mg, 16mg, 24mg).
- Guidance for switching preparations are as follows:
  - It is recommended that the same total daily dose of galantamine is administered to patients. Patients switching to the once-daily regimen should take their last dose of galantamine tablets or oral solution in the evening and start prolonged- release capsules once daily the following morning.

## COMMERCIAL-SENSITIVE

- In addition, galantamine oral solution 4mg/ml and 20mg/5ml is also readily available.

### Hypovase (prazosin) 1mg tablets

- Pfizer the sole supplier of Hypovase 1mg tablets are out of stock until the end of October.
- Hypovase 0.5mg tablets are available but cannot uplift demand for the 1mg strength.
- UKMI have advised that the following: Prazosin (Hypovase) is licensed for the treatment of hypertension and benign prostatic hyperplasia (BPH). If stock is depleted, there are other alpha blockers that patients can be switched to:
  - Doxazosin and terazosin are approved for both these indications
  - Tamsulosin and alfuzosin are licensed to treat BPH.
- There are no direct dose conversion data, so treatment should be titrated according to the patient's clinical response.
- Although prazosin is also licensed for treating heart failure and Raynaud's disease (RD), alpha blockers do not feature in heart failure guidelines and prazosin is not considered effective for RD.
- Until the shortage resolves, prescribers should not start new patients on prazosin and use of the 0.5mg strength should be restricted to current users to avoid depletion of that stock.

### Megace (megestrol) 160mg tablets

- Sobi, sole supplier of Megace tablets, are out of stock until end September 2019.
- Unlicensed imports are available. Lead times may vary.

### Mianserin 10mg/30mg tablets

- Mylan, sole supplier of mianserin tablets, are out of stock of both strengths until the end of 2019.
- For patients who do not have sufficient supplies of mianserin tablets for the duration of the expected out of stock period, **clinicians should consider prescribing an unlicensed preparation** of mianserin tablets as soon as possible in order to avoid abrupt withdrawal.
- DHSC have contacted specialist importer companies who have advised that unlicensed imports can be sourced from abroad. Lead times may vary.
- In order for pharmacies to dispense an unlicensed drug, FP10 prescriptions must indicate that a special is required/prescribed by the GP. This could include the GP annotating the prescription with the following wording: "special order".
- For patients in whom unlicensed imports are not appropriate, DHSC have commissioned clinical advice which recommends:

#### Patients who have been prescribed mianserin for < 6 months

1. GP to start mirtazapine at a low dose depending on clinical judgement and the Summary of Product Characteristics (SPC)
2. Consider psychological therapies

#### Patients who have been prescribed mianserin for > 6 months

1. GP to start mirtazapine at a low dose depending on clinical judgement and the SPC
2. Seek specialist secondary care advice on management options

COMMERCIAL-SENSITIVE

Nardil (phenelzine sulfate ) 15mg tablets

- Kyowa Kirin, the sole supplier of Nardil (phenelzine sulfate) 15mg tablets in the UK, are out of stock until at least the end of October 2019 due to manufacturing delays.
- Unlicensed imports are available from the following specialist importer companies: Clinigen, Target, Alium, Mawdsleys, Durbin, WEP Clinical and Waymade. Lead times may vary.
- Unlicensed imports can be obtained through normal wholesaler routes. If unable to obtain through wholesaler's pharmacists are advised to contact the relevant specialist importers directly.
- UK Medicine Information have also published guidance on management including the need for specialist referral to mental health teams if unlicensed supplies of phenelzine sulfate 15mg tablets are deemed unsuitable: <https://www.sps.nhs.uk/articles/shortage-of-phenelzine-15mg-tablets-nardil/>

Zidovudine 250mg capsules

- Aurobindo-Milpharm are out of stock of zidovudine 250mg capsules with no date for resupply.
- They currently have stock of 100mg zidovudine capsules available.
- ViiV Healthcare will be making additional stock of zidovudine 250mg capsules available which will be accessible for Trusts to purchase from early November 2019.
- Please see the below prescribing information from NHSE formulated with input from HIV clinical leads for guidance until the November resupply:

Usual zidovudine adult dosing regimen	Utilisation of 100mg capsules
250mg twice daily	100mg capsules
	(asymmetric dosing e.g. 200mg in the morning +300mg at night)
300mg twice daily	100mg capsules
	(3 x100mg twice a day)
200mg three times daily	100mg capsules
	(2 x 100mg twice a day)

Others

Capsaicin (Zacin) 0.025%/(Axsain) 0.075% cream

- Teva, sole supplier of capsaicin 0.025% and 0.075% creams, are out of stock until November 2019, at the earliest.
- DHSC have contacted specialist importer companies who have advised that unlicensed imports can be sourced from abroad. Lead times may vary.
- In order for pharmacies to dispense an unlicensed drug, FP10 prescriptions must indicate that a special is required/prescribed by the GP. This could include the GP annotating the prescription with the following wording: "special order".
- For patients in whom unlicensed imports are not appropriate, UKMI have produced a clinical memo on alternative treatments available at the following link: <https://www.sps.nhs.uk/articles/shortage-of-capsaicin-cream-zacin-and-axsain/>

Efudix (fluorouracil) 5% cream

- Mylan, sole supplier of fluorouracil 5% cream, are out of stock until w/e 20th September 2019.
- Limited supplies of a parallel import are available (considered licensed in the UK).



#### COMMERCIAL-SENSITIVE

- Unlicensed imports are also available. Lead times may vary.

#### Flamazine (silver sulfadiazine) 1% cream

- Smith and Nephew, supplier of Flamazine cream, are out of stock until the end of September 2019.
- Unlicensed imports are available; lead times may vary.

## Ongoing Issues

### Injectables

#### Acetylcholine Chloride (Miochol-E) 20mg powder and solvent for irrigation

- Bausch and Lomb anticipate being out of stock until the end of October due to manufacturing delays
- We have been working with alternative suppliers Farmigea, who are able to supply Miphtel 20mg ampoules available from Alloga (PIP code 3957834).
- UKMI have issued the following regarding switching to ampoules:  
<https://www.sps.nhs.uk/articles/shortage-of-miochol-e-acetylcholine-20mg-powder-and-solvent-for-solution-for-intraocular-irrigation/>
- DHSC can also confirm that unlicensed Miochol-E is available from specialist importers, lead times can vary.

#### Aciclovir 500mg/1g injection

- Several suppliers are currently experiencing issues with availability of aciclovir injection with resupply expected in September.
- Review 500mg and 1gram usage and order unlicensed imports now. Lead times may vary.

#### Amikacin 500mg/2ml injection

- Pfizer are out of stock of amikacin 500mg/2ml injection with a resupply around the end of September.
- Unlicensed imports are available in sufficient quantities to support the market during this out of stock period; lead times vary.
- Please contact your regional lead for further details about unlicensed import availability.

#### Emerade 500 microgram and 300 microgram adrenaline auto-injector (AAI) devices

- Bausch & Lomb UK, the sole suppliers of Emerade 500 microgram and 300 microgram AAI devices, are experiencing a short-term disruption in supply of these products:
  - Emerade 500 microgram AAIs are unavailable, there has been a delay in the release of further stock, at this stage resupply date is to be confirmed.
  - Emerade 300 microgram AAI are unavailable there has been a delay in the release of further stock, at this stage resupply date is to be confirmed.
- A supply disruption alert has been issued via MHRA's CAS, which includes information on the issue and actions to be taken. Please see link below:
- <https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102885>
- Emerade 150 microgram AAIs remain available.
- Epipen 300microgram remains available. Jext 300microgram will available in limited amounts until mid-October.
- Epipen 150microgram and Jext 150microgram also remain available.
- **Adrenaline for anaphylaxis kits:**



## COMMERCIAL-SENSITIVE

- Some healthcare professionals may be holding Emerade, or other Adrenaline Auto-Injectors (AAs), in preference to adrenaline ampoules, to treat anaphylactic reactions; this should not be necessary.
- All healthcare professionals providing services where anaphylaxis treatment may be required, including but not exclusive to flu vaccination services, should have the competency to draw up and administer intramuscular adrenaline from ampoules with a normal syringe and needle.
- Due to the current shortage of Emerade devices, we ask that, when renewing the adrenaline in your anaphylaxis kits, all staff are alerted to please stock ampoules (ensuring you also include dosing charts, needles and syringes) and not AAs.
- The [Green Book](#) and [Resuscitation Council](#) guidance provides additional advice to healthcare professionals on the use of adrenaline in response to anaphylaxis. Pharmacists providing vaccination services may also wish to refer to [PSNC FAQs](#). There is an expectation that healthcare professionals should use adrenaline ampoules in preference to Emerade or similar devices.

### EpiPen and EpiPen Junior

- The supply situation for EpiPen and EpiPen Junior continues to improve, and further stock due in the coming months.
- Stock of EpiPen Junior is no longer subject to prescription validation and is available to order from wholesalers. Please order in line with demand, Mylan and DHSC will review stock levels regularly to ensure sufficient supplies remain available.
- Stock of EpiPen 0.3mg device is available via a prescription validation process. Information about this process is available on the EpiPen website under the 'Instruction to Pharmacists' section: <http://www.epipen.co.uk/>
- Hospitals are advised to contact Alliance if they wish to obtain EpiPen 0.3mg.

### Erwinase injection

- Porton Biopharma, the manufacturer of Erwinase, have had ongoing manufacturing issues affecting this product for the past 1-2 years.
- Jazz Pharmaceuticals distributes Erwinase and are now out of stock.
- Further batches are currently expected to be available in September.
- There are likely to be ongoing intermittent supply issues which will continue during 2019.
- Jazz works closely with the clinical networks and supplies are prioritised on a patient need basis and in conjunction with the treating clinicians.

### Haloperidol 5mg/ml injection

- Advanz Pharma are out of stock of haloperidol 5mg/ml injection until end of September.
- DrugsRUs, have confirmed they have sufficient supplies available to meet additional demand during this period.

### Idarubicin 10mg injection (Zavedos)

- Pfizer are out of stock of UK licensed idarubicin 10mg injection until w/c 16<sup>th</sup> September 2019.
- Pfizer are supplying an unlicensed Ready-To-Use preparation from Australia in the interim.

### Labetalol 5mg/mL injection

- Recipharm are currently out of stock of labetalol 5mg/mL (20ml) injection due to an API issue and anticipate further supplies to become available in December 2019.

#### COMMERCIAL-SENSITIVE

- Synchrony Pharma, who also manufacture labetalol 5mg/mL (10ml) injection, have experienced a delay in the next delivery of labetalol which will lead to a very short out of stock period with further stock expected on 13<sup>th</sup> September 2019.
- Synchrony stock can be ordered from Alloga.
- If Trusts do not have sufficient stock to last until the resupply date, contact your regional procurement lead who may support stock sharing between Trusts.

#### Neurobloc (Botulinum Toxin Type B)

- Neurobloc (Botulinum Toxin Type B) will not be available until mid-October due to the product being divested from Eisai to Sloan Pharma.
- DHSC has worked with the specialist importers and can confirm that unlicensed Botulinum Toxin Type B is available; lead times vary.

#### Oncaspar (pegaspargase) 750 U/ml solution for injection/infusion

- Servier will be supplying Oncaspar in Irish packaging from July until October 2019 due to supply issues with the UK packaging.
- There is no difference to the product. Differences in the packaging and the PIL are detailed on the Dear Healthcare Professional letter (attached).

#### Tetracosactide 1mg depot injection

- Mallinckrodt have informed DHSC that tetracosactide 1mg depot injection will be unavailable until the second half of 2019.
- Specialist importers have sourced an unlicensed product.
- NHS Trusts should continue to order unlicensed stock from the specialist importers. Further information has been circulated to regional procurement specialists.

#### Tobramycin 240mg/6ml injection

- Pfizer are out of stock of tobramycin 240mg/6ml injection until w/c 7<sup>th</sup> October.
- There is sufficient 80mg/2ml available from both Pfizer and Flynn (via Alloga) to cover full usage and Trusts are advised to switch to this strength during the out of stock period.
- Reserve any 240mg/6ml injection for patients who are unable to switch to the 80mg/2ml, for example, those who use via a nebuliser.

#### Urokinase injection

- Syner-med are currently out of stock of urokinase strengths, 10,000unit, and 100,000 unit, with limited supplies of 25,000IU. Further detail is provided below:
  - 10,000IU – further stock available late September;
  - 25,000IU – in stock; supply restrictions to remain in place until late September to ensure stock remains available.
  - 100,000IU – further stock available late September.
- We are aware that unlicensed imports are not readily available or in sufficient quantities to fully meet demand during this time and therefore Trusts are asked to review their current usage of urokinase and consider using an alternative product. Details of suggested alternative products can be found in a memo produced by UKMi (see below).
- <https://www.sps.nhs.uk/articles/shortage-of-urokinase-injection-syner-kinase-10000-iu-25000-iu-and-100000-iu-powder-for-solution-for-injection-or-infusion/>
- We have been in contact with all the suppliers of the suggested alternatives and can confirm that they have sufficient supplies available to support during this time.

#### COMMERCIAL-SENSITIVE

- Additional information for the product Taurolock is also attached. If you would like to place orders for this product, please contact [customerservice@kimal.co.uk](mailto:customerservice@kimal.co.uk) and copy [louise.kelly@kimal.co.uk](mailto:louise.kelly@kimal.co.uk)

## Orals

### Actiq (fentanyl) lozenges

- Teva are experiencing supply issues with some strengths of Actiq lozenges with no supplies of the 200mcg or 400mcg strength available until end of September. All other strengths remain available.
- Immediate release fentanyl products are not interchangeable and when considering switching patients from one product to another, patients should not be converted on a microgram per microgram basis from one to another; it is necessary to titrate the new formulation with advice from a specialist.
- See the link below for advice from UKMI:  
<https://www.sps.nhs.uk/articles/shortage-of-actiq-lozenges-and-instanyl-nasal-spray-immediate-release-fentanyl-citrate/>

### Adalat (nifedipine) tablets/capsules

- As previously communicated, there are ongoing supply issues with the Adalat range. We have been in contact with generic suppliers and can confirm that supplies are available with additional deliveries expected in the coming weeks.
- Please see the attached letter from Bayer and the shortages memo from UKMI:  
<https://www.sps.nhs.uk/articles/shortage-of-adalat-nifedipine/>

### Bumetanide 5mg tablets

- Mylan, the sole supplier of bumetanide 5mg tablets, have informed DHSC they are out of stock of this strength with availability expected w/e 27<sup>th</sup> September 2019.
- Supplies of the 1mg tablet remain available.
- There is a bumetanide 1mg/5ml liquid available from Chemidex however there is insufficient stock to cover an uplift in demand.

### Carbagen (carbamazepine) various preparations

- As carbamazepine is considered a Category 1 anti-epileptic medication, patients should normally be maintained on the same brand, however Mylan (manufacturers of Carbagen) have informed DHSC that the following preparations of Carbagen will be unavailable until late 2019.
- The affected products are:
  - Carbagen 200mg and 400mg immediate release tablets – unavailable until late 2019
  - Carbagen 200mg and 400mg modified release tablets – unavailable until late 2019
- Patients currently prescribed Carbagen tablets by brand will therefore need to be switched to an alternative brand of carbamazepine tablets during this time.
- Novartis, the manufacturer of Tegretol tablets, which is the alternative brand of carbamazepine, have confirmed that all presentations are currently available that they are able to support additional demand during this time for all affected strengths and formulations.
- DHSC have worked with NHSE, NHSI and UK Medicines Information to develop a clinical memo, which has been produced to support clinicians in prioritising and switching patients. This is available on the SPS website via the following link: <https://www.sps.nhs.uk/articles/shortage-of-carbagen-carbamazepine-tablets/>

## COMMERCIAL-SENSITIVE

### Cefuroxime 125mg/5ml suspension (Zinnat)

- GSK the sole supplier of cefuroxime 125mg/5ml suspension will be out of stock until 18<sup>th</sup> September 2019.
- Cefuroxime 125mg tablets are available from GSK.
- UKMI have advised that tablets can be crushed and dispersed for oral administration. However, please note that doing so is considered off-label use.

### Colestid (colestipol) 5g granules

- Pfizer are out of stock of Colestid orange and plain granules until mid-October and end of October, respectively.
- Clinicians should refer to the UKMI memo for advice on alternatives: <https://www.sps.nhs.uk/articles/shortage-of-bile-acid-sequestrants/>
- DHSC has worked with the specialist importers and can confirm that unlicensed Colestid is available; lead times vary.

### Disopyramide 150mg capsules

- Mylan, sole supplier of disopyramide 150mg tablets, are out of stock until end of September 2019.
- A supply disruption alert has been issued via MHRA's CAS, which includes information on the issue and actions to be taken. Please see link below: <https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102869>

### Epanutin (phenytoin) 50mg Chewable Infatabs

- Pfizer have a temporary supply issue with Epanutin Infatabs until November 2019 due to a delay in manufacturing.
- To help mitigate the shortage Pfizer has obtained approval from the MHRA to import stock of Dilantin (phenytoin) Infatabs from Canada.
- Canadian packs of Dilantin are considered as an unlicensed product in the UK. A copy of the product information and the DHCP letter can be found attached to this update.
- Epanutin 30 mg/5 ml Oral Suspension is currently experiencing a supply issue (see above) and as such patients should not be switched to Epanutin Oral Suspension.

### Heminevrin (clomethiazole) 192mg capsules

- Cheplapharm, the sole supplier of Clomethiazole 192mg Capsules have a short-term supply issue due to packaging issues.
- Cheplapharm anticipate the resupply date to be the end of September.
- They manufacture Heminerin (Clomethiazole) 31.5mg/ml syrup, however, there is insufficient supplies to meet any additional demand.
- We have been working with the importers who have confirmed that limited supplies are available – hospitals requiring stock should place orders NOW for unlicensed imports as lead times will vary.
- UKMI have prepared the following shortages memo, which has been published on the SPS website: <https://www.sps.nhs.uk/articles/shortage-of-heminevrin-clomethiazole-192-mg-capsules/>

### Hormone Replacement Therapy products (HRT)

Please see Table. 2 in the Appendix for a full list of currently available HRT products.

## COMMERCIAL-SENSITIVE

### *FemSeven Products*

- Theramex, the supplier of FemSeven Conti and Sequi patches are experiencing long term supply issues affecting both products and expect to be out of stock until late 2019.
- This supply issue does not affect supplies of FemSeven Mono.
- Supplies of other HRT patches and products continue to remain available.

### *Evorel Products \*\**

\*\*See table

- 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 in the Appendix.
- 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/>

### *Elleste Range \**

\*See table

- Mylan have recently advised that supplies of the majority of the Elleste Range ( Elleste Duet 1mg and 2mg tablets, Elleste solo 1mg and 2mg tablets, 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.

Table 1. Equivalent HRT alternatives for the Elleste HRT range

Brand	Ingredient(s)	Current Availability	Equivalent	Ingredient(s)	Current Availability
Elleste Solo 1mg	estradiol hemihydrate	In stock	Progynova 1mg	estradiol hemihydrate	In stock
			Zumenon 1mg		OOS
Elleste Solo 2mg	estradiol hemihydrate	In stock	Progynova 2mg	estradiol hemihydrate	In stock
			Zumenon 2mg		In Stock
Elleste Duet Conti	estradiol 2mg/ norethisterone 1mg	In stock at the wholesalers	Kliofem	estradiol 2mg/ norethisterone 1mg	In Stock
Elleste Duet 1mg	estradiol 1mg/ norethisterone 1mg	In stock	NovoFem	estradiol 1mg/ norethisterone 1mg	In Stock

### *Indivina (Estradiol/ Medroxyprogesterone) 2mg/5mg tablets*

- Orion, the sole manufacturer of Indivina 2mg/5mg HRT tablets have reported that they will be out of stock of this strength until end of December 2019.

#### COMMERCIAL-SENSITIVE

- Orion have advised there is sufficient stock of Indivina 1mg/2.5mg tablets (lower strength) to cover an uplift in demand until the higher strength is back in stock.
- Please note patients normally prescribed the higher strength of Indivina (2mg/5mg), would require two tablets of the lower strength (1mg/2.5mg) to ensure equivalence.

#### *Zumenon (estradiol) 1mg tablets*

- Mylan have notified the DHSC that due to manufacturing capacity constraints there would be a short interruption in supply.
- Currently, Mylan are out of stock of the 1mg tablets and resupply is anticipated at the beginning-middle of September 2019.

#### Metoprolol 50mg and 100mg tablets

- There are ongoing supply issues affecting metoprolol 50mg and 100mg tablets.
- The issue has been caused by some manufacturers discontinuing the products and others having supply difficulties.
- Milpharm/Aurobindo, are currently the sole supplier of both presentations to the UK market.
- Supplies of both presentations are currently available but may be limited, supply is likely to be intermittent for several months.
- Please see the link below for a memo developed by UK Medicine Information with input from clinical experts at NHSE and NHSI, which advises on management options for patients affected by this supply issue, including the use of alternative beta blockers, dosing information for these alternative beta blockers and monitoring requirements. <https://www.sps.nhs.uk/articles/shortage-of-metoprolol-50mg-and-100mg-tablets/>
- The manufacturer of carvedilol has indicated it would be unable to meet demand if patients were switched to this product. Manufacturers of bisoprolol, atenolol and propranolol have indicated they have capacity to support any additional demand on their products.

#### Olena (fluoxetine) 20mg dispersible tablets

- Advanz Pharma, the sole manufacturer of fluoxetine 20mg dispersible tablets, are currently out of stock; further supplies are expected in October 2019.
- An oral solution, fluoxetine 20mg/5ml, is available from alternative manufacturers.

#### Oral Contraceptive Pill products (OCP)

##### *Loestrin 20 and Loestrin 30 tablets*

- Galen Limited are currently out of stock Loestrin 20 tablets and anticipate they will go out of stock of Loestrin 30 tablets at the beginning of June and are currently unable to provide a resupply date.
- Galen Limited have produced the attached *Dear Health Care Professional* letter providing further details on the issue.

##### *Noriday (norethisterone) 350 micrograms tablets*

- Pfizer, the supplier of the oral contraceptive pill, Noriday, have advised that due to a delay at the manufacturing site, it will be out of stock until end of September.
- UKMI have advised that there are no exact equivalent preparations in the UK market and clinicians should refer to CKS guidance for advice on alternative POPs:  
<https://cks.nice.org.uk/contraception-progestogen-only-methods#!scenario:>

##### *Norimin (ethinylestradiol/norethisterone) 0.035mg/1mg tablets*

- Pfizer, the supplier of the OCP Norimin, have advised due to delay at the manufacturing site, Norimin will be OOS until the end of September.

## COMMERCIAL-SENSITIVE

- UKMI have advised that there are no exact equivalent preparations to Norimin available in the UK market.
- Other ethinylestradiol and norethisterone OCP products should be available.
- Clinicians are advised to refer to CKS guidance for advice COCs:  
<https://cks.nice.org.uk/contraception-combined-hormonal-methods>

### Physeptone (methadone) 5mg tablets

- DHSC have been made aware of a supply issue with methadone (Physeptone) 5mg tablets from the sole licensed UK supplier, Ethypharm.
- Ethypharm are currently out of stock due to a packing issue with their contract manufacturer. Further stock is now expected 20<sup>th</sup> September 2019.
- During this time unlicensed methadone 5mg capsules are being manufactured and can be ordered directly from Ethypharm. The product code is **P034663** - Methadone Capsules 5mg 50 [CD]. Please allow 1-2 days delivery for the unlicensed supply.
- Clinicians can prescribe unlicensed products for their patients if they think it appropriate, on an individual patient basis, but do so entirely on their own responsibility.
- Other presentations of methadone, including suspension, remain available.

### Questran Powder for Oral Suspension

- Bristol-Myers Squibb (BMS) divested the entire Questran range to Cheplapharm at the end of July 2019.
- Cheplapharm are out of stock of Questran Powder 4g sachets until mid-2020.
- Supplies of Questran Light are currently available through Alliance Healthcare.

### Quinapril 5mg/10mg tablets

- Both suppliers of quinapril 5mg are out of stock until at least the middle of September.
- Supplies of the 10mg are in limited supply, however the 20mg tablets remain available from Pfizer
- UKMI have issued the following advice regarding halving the 10mg/ 20mg scored tablets:
  - The 10mg and 20mg quinapril tablets are scored, however manufacturers state this scored line is for facilitating breaking of tablets for ease of swallowing and may not divide in equal doses. It is unlikely that the distribution in the tablet will be significantly different in the two halves. Therefore, the majority of patients should not experience problems with splitting tablets and taking half of a 10mg tablet to equate 5mg dose.
- Alternatives to this, are to switch to an alternative ACE-Inhibitor (Captopril, Enalapril, Fosinopril, Imidapril, Lisinopril, Perindopril, Ramipril, Trandolapril). There are no guidelines on converting doses between ACE Inhibitors, considering the 5mg of Quinapril is the lowest dose, it is recommended starting patients on lowest strengths of available ACE-Inhibitors and titrate doses upwards according to patient response.

### Sinemet 10/100mg tablets

- Merck Sharp and Dohme (MSD) are out of stock of Sinemet 10/100mg tablets due to capacity constraints.
- MSD have received further stock but anticipate supplies of this product will be intermittent until October 2019.
- DHSC has confirmed with alternative generic suppliers of co-careldopa 10/100mg tablets that they have sufficient quantities to cover this out of stock period.



## COMMERCIAL-SENSITIVE

### Stemetil (prochlorperazine) 5mg in 5ml oral syrup

- Sanofi are out of stock of Stemetil oral syrup until end of November 2019.
- Other presentations of prochlorperazine remaining are:
  - Buccal (maleate) 3mg
  - Injection (mesylate) 12.5mg
  - Tablets (maleate) 5mg
- UKMI have prepared the following shortages memo, which provides potential advice on management options:  
<https://www.sps.nhs.uk/articles/shortage-of-stemetil-prochlorperazine-5mg-5ml-syrup/>

### Tiagabine tablets

- Teva, sole supplier of tiagabine tablets, are out of stock of all strengths until the end of October 2019.
- A limited amount of stock remains available through Alliance Healthcare. If pharmacies are unable to obtain from their usual depot, inform Teva customer services who will liaise with the wholesaler to redistribute stock to where it is required.
- We are aware that unlicensed supplies of tiagabine tablets are available from importers. Lead times may vary.
- In order for pharmacies to dispense an unlicensed drug, FP10 prescriptions must indicate that a special is required/prescribed by the GP. This could include the GP annotating the prescription with the following wording: "special order".
- Once licensed stock is exhausted and if unlicensed medication is not considered appropriate, patients who do not have enough supplies to last until end of October, should be encouraged to return to their clinician for specialist advice.

### Trifluoperazine tablets

- There have been ongoing manufacturing issues affecting trifluoperazine 1mg and 5mg tablets causing long term issues with supplies not expected before mid-2020.
- Concordia and Rosemont have trifluoperazine liquid and good supplies are available.
- We are aware that unlicensed supplies of the 1mg and 5mg tablet are available from both Ennogen and several other specialist importer companies.

### Tuberculosis medications

#### *Ethambutol 100mg tablets*

- Thornton & Ross, framework holders for LSNE, are out of stock of this product until 18th September.
- Morningside are in stock but are unable to support the LSNE region during this time.
- Trusts affected should review local stock holding and consider dispensing ethambutol prescriptions in instalments to ensure continuity of supply to patients until expected replenishment date.
- Following this, if Trusts are unable to ensure continuity of supply, contact your regional procurement lead who will support stock sharing between Trusts.

#### *Pyrazinamide 500mg tablets*

- Both suppliers of pyrazinamide 500mg tablets are currently experiencing supply issues.
- Morningside, who support the CESW region, are out of stock; resupply expected by November 2019.
- Thornton & Ross are also out of stock with resupply expected by w/e 13<sup>th</sup> September 2019 after which they can support the CESW region.

## COMMERCIAL-SENSITIVE

- DHSC can confirm that unlicensed pyrazinamide tablets are available from specialist importers, lead times can vary.

### *Rifadin (rifampicin) 150mg capsules*

- Sanofi are out of stock of Rifadin 150mg capsules with resupply expected w/c 16<sup>th</sup> September.
- Mylan can support this out of stock period.
- Review local stock holding. If stock is required, place orders with Mylan for 150mg capsules.
- Order in line with historic demand to ensure stocks are not depleted rapidly.

### *Rifater tablets*

- Sanofi, the sole supplier of this combination anti-tuberculosis product is experiencing a delay in its manufacture with resupply now stated as end of October.
- Supplies of a parallel imported product (considered licensed UK stock) are available from Alliance Healthcare. Trusts are asked to only order according to historical demand for the duration of the out of stock period.
- Further supplies of parallel imported product are not currently assured and therefore Trust should review local stock holding in light of the Sanofi shortage extension and start placing orders with importers.
- DHSC can also confirm that unlicensed *Rifater* tablets are currently available from specialist importers; lead times can vary.

## Others

### *Dalacin (clindamycin) 2% vaginal cream*

- Pfizer, sole supplier of clindamycin 2% vaginal cream, are out of stock until end of September at the earliest due to delays in packaging.
- There are two other topical products licensed for the treatment of bacterial vaginosis:
  - Zidoval (metronidazole 0.75% w/w) vaginal gel (one application [5g] inserted into the vagina once daily, at bedtime, for 5 consecutive days)
  - Fluomizin (dequalinium chloride 10 mg) vaginal tablets (one vaginal tablet daily, at bedtime, for 6 days)
- Please refer to local formulary and guidelines for management of bacterial vaginosis which also cover systemic therapies. CKS guidance is also available: <https://cks.nice.org.uk/bacterial-vaginosis>

### *Indocid (indometacin) 100mg suppositories*

- Aspen, sole supplier of this product are out of stock until early October 2019.
- Supplies of parallel imported products (considered licensed UK stock) are available.

### *Instanyl (fentanyl) nasal spray*

- Takeda are currently out of stock of some strengths of Instanyl nasal spray with resupply date as follows: 100mcg mid-September; 200mcg mid-September.
- Instanyl 50mcg nasal sprays are available.
- Immediate release fentanyl products are not interchangeable and when considering switching patients from one product to another, patients should not be converted on a microgram per microgram basis from one to another; it is necessary to titrate the new formulation with advice from a specialist.
- See the link below for advice from UKMI:

COMMERCIAL-SENSITIVE

<https://www.sps.nhs.uk/articles/shortage-of-actiq-lozenges-and-instanyl-nasal-spray-immediate-release-fentanyl-citrate/>

#### Nitrous Oxide and Entonox

- BOC have experienced recent manufacturing issues with Nitrous Oxide and Entonox.
- Stock of both products is currently being closely managed and lead times for delivery is currently two days.
- BOC have provided an updated Dear HCP which is attached.
- If Trusts are having difficulty obtaining stock, they are advised to contact their local BOC account managers.

#### Skinoren (azelaic acid) 20% cream

- Leo Pharma have taken over distribution of Skinoren cream and are currently out of stock with resupply expected early 2020.
- UKMI has provided the following advice on alternative options:
  - Azelaic acid has antimicrobial and anticomedonal properties and is considered less likely to cause local irritation than benzoyl peroxide; it is an alternative in facial acne if benzoyl peroxide or topical retinoid poorly tolerated.
  - There are other topical products available and choice will be determined by what patient has already tried/ tolerated. Systemic treatments are also an option
  - Please refer to local formulary or to following guidelines for alternative treatment options:
  - NICE Clinical Knowledge Summary (April 2018): <https://cks.nice.org.uk/acne-vulgaris#!scenarioRecommendation>
  - Primary Care Dermatology Society ( April 2019): <http://www.pcds.org.uk/clinical-guidance/acne-vulgaris#management>

#### Zentiva: distribution issues

- Zentiva's UK logistics provider (Kuehne and Nagel) experienced a technical issue with one of their IT systems which impacted on their ability to get stock to their agent's depots.
- Normal stock levels are expected to be restored by during September 2019. Back orders will be cancelled. Please place new orders when stock becomes available at local depots.

## Eye drops/treatments

### **Allergan**

#### Lacri-Lube

- out of stock due to an ongoing manufacturing issue. Allergan are unable to provide a re-supply date at this stage.
- The Royal College of Ophthalmology is aware of the Lacri-Lube shortage and is recommending Xailin Night Ointment. <https://www.rcophth.ac.uk/standards-publications-research/quality-and-safety/medicines-safety/drugs-shortages/>.

### **Bausch and Lomb**

#### Lotemax

- out of stock until end of September

## COMMERCIAL-SENSITIVE

### Phenylephrine 10% Minims

- out of stock until early December

### Ethypharm

#### Chloramphenicol 0.5% eye drops

- Discontinuation of POM product only
- Ethypharm have confirmed that chloramphenicol eye drops remain available as a P-product

### RPH Pharmaceuticals AB

#### Betamethasone Ointment 0.1% w/w x 3g

- RPH Pharmaceuticals AB, have advised that following the discontinuation of Betnesol Eye Ointment 0.1% w/w x 3g they have experienced manufacturing problems which have resulted in the nonviability of launching a generic Betamethasone Eye Ointment 0.1% w/w x 3g.

#### Betnesol (betamethasone 0.1%) eye/ear/nose drops

- RPH Pharmaceuticals are currently out of stock of betamethasone 0.1% eye/ear/nose drops with a resupply date of late 2019. Martindale Pharma can support the full market during this time.

## Vaccines

**For updates on other vaccine supply position, please refer to PHE's Vaccine Update Bulletin found at the following address:**

<https://www.gov.uk/government/collections/vaccine-update#2019>

### Hepatitis B Vaccines

#### Renal dose

- MSD's renal vaccine HBVAXPRO 40micrograms are still out of stock of until further notice. Please see statement: <http://www.msduk.com/products/vaccines.xhtml>.
- GSK's Hepatitis B renal vaccine, Fendrix, is currently available.

#### Adult dose

- MSD are out of stock HBVAXPRO 10mcg vaccine until further notice
- GSK are confident they can support the increased demand during this time.

### Menveo (meningitis A, C, W, Y):

- GSK have confirmed there is limited supply of Menveo.
- Pfizer have confirmed they are in stock of Nimenrix and currently able to support increased demand.

### Rabipur (Rabies vaccine)

- Limited supply of GSK's Rabipur is currently available. Supply issues resulting from manufacturing constraints have now resolved, however, GSK do not expect the situation to fully normalise until late 2019.
- Sanofi Pasteur have confirmed they are able to support the full market during this time with their unlicensed Rabies vaccine, Verorab

COMMERCIAL-SENSITIVE

- NATHNAC have issued further information available at the following link:  
<https://travelhealthpro.org.uk/news/389/rabies-vaccine-availability>

## Discontinuations

### Adasuve (loxapine) 9.1mg inhalation powder (Ferrer)

- Due to a temporary discontinuation the company is not marketing Adasuve from 31 July 2019

### Ammonaps (sodium phenylbutyrate) 940mg/g granules (SOBI)

- Following the shortage of Ammonaps granules in May, the company has now informed us that they are unable to resolve the supply problem and intend to discontinue with immediate effect
- SOBI have confirmed that they have good supplies of the alternatives listed below:

#### Possible alternatives to Ammonap granules:

Product	Active ingredient	Strength	Form
Ammonaps	Sodium phenylbutyrate	500 mg	Tablets
Ravicti	Glycerol phenylbutyrate	1.1 g/ml	Oral solution

### Bovine Insulin (Wockhardt)

- The final remaining bovine presentations will not be supplied after end August 19
- The latest information is available on the company website at the following link:  
<http://www.wockhardt.co.uk/our-products/bovine-insulin-hcp-information.aspx>

### Cilest (norgestimate 250mcg and ethinylestradiol 35mcg) tablets (Janssen-Cilag)

- Janssen Cilag is discontinuing Cilest (norgestimate 250 mcg and ethinylestradiol 35 mcg) and expects stocks to be exhausted by the end of July
- We have been in contact with other suppliers of norgestimate 250 mcg and ethinylestradiol 35 mcg and have confirmed that the alternatives Cilique (Consilient) and Lizianna (Morningside) are both fully available and able to meet any increase in demand.

### Dexamfetamine 1mg/1ml oral solution (Ethypharm)

- Ethypharm has informed us they have discontinued dexamfetamine 1mg/ml oral solution from the market with immediate effect; stocks have been exhausted
- Dexamfetamine 1mg/1ml oral solution remains available from Thame Lab; who have been informed that they are the sole supplier

## COMMERCIAL-SENSITIVE

### Isotrexin Gel (isotretinoin and erythromycin) (Stiefel)

- Stiefel plans to discontinue Isotrexin from market in December 2019
- Other topical products remain available

### Modecate (fluphenazine decanoate) injection

- Manufacture of Modecate (fluphenazine decanoate) injection has ceased
- Existing stock of Modecate Injection (25 mg/ml) will expire in August 2019 – supplies should be ordered now to treat any patients who have yet to be switched to an alternative treatment.
- Existing stock of Modecate Concentrate Injection (100 mg/ml) will expire in August 2020 – stock will not be released after 29 February 2020.
- Prescribers should complete arrangements to transfer patients on Modecate to therapeutic alternatives under medical supervision.
- Some unlicensed importer companies have confirmed that they can source supplies of unlicensed fluphenazine decanoate injection from abroad going forward.

### Sebivo (telbivudine) 600mg film-coated tablets (Novartis)

- Novartis plans to discontinue Sebivo tablets from the market in October 2019
- There are no other MA holders for telbivudine
- However, there are other antiviral agents available for hep B

### Stayveer (bosentan) tablets (Janssen-Cilag)

- Janssen-Cilag is discontinuing Stayveer tablets from the market in September 2019
- Tracleer brand to remain available
- Generic bosentan tablets also remain available from a number of alternative suppliers

### Tilade (nedocromil sodium 2mg/dose) Inhaler

- Sanofi has discontinued Tilade inhaler following the earlier supplier problem.
- They are the sole supplier of nedocromil sodium inhaler.
- UKMI have advised that Intal (Sodium Cromoglicate-5mg/dose) is interchangeable and we have confirmed with Sanofi that sufficient stock is available.
- Please note differences in maintenance doses for these inhalers: -
  - Sodium cromoglicate (Intal) - Initially TWO puffs (10 mg) four times a day, additional dose may also be taken before exercise, increased if necessary, to TWO puffs (10 mg) six to eight times a day. Maintenance dose is ONE puff (5 mg) four times a day.
  - Nedocromil sodium (Tilade)- Initially TWO puffs (4 mg) four times a day, when control achieved, may be possible to reduce to twice daily.
  - For further information visit: <https://cks.nice.org.uk/asthma#!prescribingInfoSub:21>

COMMERCIAL-SENSITIVE

## Resolved (date resolved)

Actiq (fentanyl) 600mcg lozenges (5/9/19)  
 BOC Medical Carbon Dioxide (29/8/19)  
 Bufyl (bupivacaine 1mg/ml and fentanyl 2 micrograms/ml) solution for infusion 250ml (6/9/19)  
 Cardura XL (doxazosin) 4mg/8mg tablets (27/8/19)  
 Disopyramide 100mg capsules (22/8/19)  
 Epanutin (phenytoin) 30mg/5ml oral suspension (9/9/19)  
**Stock are available through Pfizer's customer care centre**

Fludarabine 50mg/2ml injection (16/8/19)  
 Gadovist preparations 02/08/2019  
 Joyrides (hyoscine hydrobromide 150 microgram) tablets (20/8/19)  
 Ketalar 200mg in 20ml (ketamine hydrochloride 10mg/ml) injection (16/8/19)  
 Mivacron (mivacurium chloride) injection (5/9/19)  
 Ovrnette (ethinylestradiol 30 mcg/levonorgestrel 150mcg) tablets (4/9/19)  
 Phenylephrine 1mg in 10ml (0.1mg /ml) injection (2/9/19)  
 Prostin E2 (dinoprostone) 3mg Vaginal Tablet (10/9/19)  
 Rifadin (rifampicin) 300mg capsules (27/8/19)  
 Sanofi: distribution issues (26/8/19)

## Appendix

**Table 2 Current HRT Availability**

Ingredient (s)	Manufacturer	Oestrogen Only			Anticipated resupply date	
		Brand	Strength	Current Availability		
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	In stock		
Estradiol valerate	Bayer	Progynova	1mg	In stock		
			2mg	In stock		
Estradiol	Resource Medical UK	Bedol	2mg	Long term OOS		
Conjugated oestrogen	Pfizer	Premarin	300mcg	In stock		



COMMERCIAL-SENSITIVE

			625mcg	In stock	
			1.25mg	In stock	
<b>Transdermal patches</b>					
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	Limited Stock	Mid-September 2019
	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		
		80mcg	In stock		
<b>Topical (Transdermal gels/creams/other delivery systems)</b>					
Estradiol	Besins Healthcare (UK) Ltd	Oestrogel	0.06%	In stock	
Estradiol hemihydrate	Orion	Sandrena	0.5mg	OOS at Orion In stock at wholesalers	
			1mg (28)	In stock	
			1mg (91)	OOS	Mid-September 2019

COMMERCIAL-SENSITIVE

	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	
<b>Progestogen only</b>					
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	
<b>Combined HRTs (Progestogen and oestrogen)</b>					
<b>Continuous combined therapy</b>					
<b>Oral preparations</b>					
Estradiol hemihydrate / norethisterone acetate	Mylan	Elleste Duet Conti*	2mg / 1mg	In stock at wholesalers	Continued availability to be confirmed
	Novo Nordisk	Kliefem	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 2019.
			1mg/5mg	In stock	
low dose conjugated oestrogen/medroxyprogesterone	Pfizer	Premique	300mcg/1.5mg	In stock	
<b>Transdermal patch</b>					
Estradiol hemihydrate/ norethisterone acetate	Janssen-Cilag	Evorel Conti **	3.2mg/11.2mg	In stock - mid to end of October 2019	Mid 2020 See below **

COMMERCIAL-SENSITIVE

Estradiol hemihydrate/ levonorgestrel	Theramex	FemSeven  Conti	1.5mg/ 0.525mg	Long term OOS	Q2 2020
<b>Sequential combined therapy</b>					
<b>Oral preparations</b>					
Estradiol [X,X] / norethisterone acetate	Resource Medical UK	Clinorette	[2mg, 2mg]/ 1mg	Long term OOS	
Estradiol/norgestrel	Mylan	Cyclo-progynova	2mg/500mcg	Long term OOS	Continued availability to be confirmed
Estradiol hemihydrate / norethisterone acetate		Elleste Duet *	1mg/ 1mg	In stock	
			2mg/ 1mg	In stock	
Estradiol hemihydrate/ dydrogesterone		Femoston	1mg/ 10mg	In stock	
	2mg/10mg		In stock		
Estradiol hemihydrate / norethisterone acetate	Novo Nordisk	Novofem	1mg/ 1mg	In stock	
Estradiol valerate/ medroxyprogesterone acetate		Trisequens	[2mg, 2mg, 1mg]/ 1mg	In stock	
Estradiol hemihydrate [X,X,X]/ norethisterone acetate	Orion	Tridestra	2mg/20mg	In stock	
<b>Transdermal patch</b>					
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
<b>Gonadomimetic (s)</b>					
Tibolone 2.5mg	Advanz Pharma	Livial tablets	Tibolone 2.5mg	In stock	
<b>Selective oestrogen receptor modulator</b>					
Ospemifene 60mg tablets	Shionogi	Senshio tablets	Ospemifene 60mg tablets	In stock	
<b>Tissue-selective oestrogen complex</b>					
Conjugated oestrogen 300mcg/ bazedoxifene 20mg	Pfizer	Duavive	conjugated oestrogen 300mcg/ bazedoxifene 20mg	In stock	