

COMMERCIAL-SENSITIVE

Supply Issues Update for Primary and Secondary Care: March/April 2020

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/>

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Information provided w/c 30 March 2020

New Issues

Injectables

Diazepam (Diazemuls) 10mg/2ml emulsion for injection

- Accord are out of stock until Q4 2020
- An MSN was shared on the 27th March 2020, please see attachment for further information.
- UKMi have prepared a clinical memo to support management of this issue (see link below):
<https://www.sps.nhs.uk/articles/shortage-of-diazemuls-diazepam-5mgml-emulsion-for-injection/>
- NOTE: There are insufficient supplies of Ativan injection to support, please do not use in place of Diazemuls.

Gadovist preparations

- Bayer are experiencing ongoing manufacturing issue at their site in Berlin is affecting supplies of their Gadovist presentations. This issue is due to be resolved in early June 2020
- We have engaged with Bracco and Guerbet regarding their supply position on other gadolinium containing products. Both companies have good supplies available and have sufficient stock to support this supply issue
- Please see full summary/stock position in table below:

Manufacturer	Presentation	Stock Availability
Bayer Plc	Gadovist 1mmol/ml solution for injection 10ml pre-filled syringes	Currently OOS. The next scheduled in June 2020.
Bayer Plc	Gadovist 1mmol/ml solution for injection 15ml vials	Currently in stock . The stock available is expected to meet usual demand and further deliveries due in May and June 2020.
Bayer Plc	Gadovist 1mmol/ml solution for injection 5ml pre-filled syringes	Currently in stock . The stock available is expected to meet usual demand and further deliveries due in July 2020.
Bayer Plc	Gadovist 1mmol/ml solution for injection 7.5ml pre-filled syringes	Currently in stock . The stock available is expected to meet usual demand and further deliveries due in mid-June 2020.

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Bayer Plc	Magnevist 2mmol/l solution for injection 1 x 20 ml pre-filled syringe	Currently in stock . The stock available is expected to meet usual demand and further deliveries due in March and mid-June 2020.
Guerbet UK	Dotarem 5ml vial, 10ml vial, 10ml PFS, 15ml vial, 15ml PFS, 20ml vial, 20ml PFS,	All presentations in stock and Guerbet have sufficient stock to support the shortage.
Bracco UK Ltd	ProHance 0.5mmol/ml 10ml PFS, 10ml vials, 15ml vials, 17ml PFS, 20ml vials	All presentations in stock and Bracco have sufficient stock to support the shortage.

Sodium Bicarbonate for Intravenous Infusion (Polyfusors)

- The following Fresenius Kabi polyfusors are due to be out of stock between early April late October 2020: sodium bicarbonate 1.26%, 1.40%, 2.74%, and 8.4%.
- Sodium bicarbonate 4.2% Polyfusor will remain available but cannot support an uplift in demand to compensate for other lines.
- Sodium Bicarbonate 8.4% 100ml bottles (B Braun) and 10ml ampoules (Ethypharm) are available.
- UKMI have produced the following memo to support dilution:
<https://www.sps.nhs.uk/articles/shortage-of-sodium-bicarbonate-polyfusors-fresenius-kabi-all-strengths/>
- An MSN was issued on the 25 March 2020, please see attachment for further information.

Orals

Calcium Folate 15mg tablets

- Calcium folinate 15mg tablets are out of stock until July 2020.
- Specialist importers can source unlicensed products, lead times vary.

Clozapine (Zaponex) 25mg oro-dispersible tablets

- Out of stock until early April 2020.
- Leyden Delta have sufficient supply of Zaponex 12.5 mg oral dispersible tablets and 25 mg tablets to support and are discussing options with each customer at the point of ordering.

Cycloserine 250mg capsules

- Out of stock with no current resupply date.
- Specialist importers can source unlicensed products. Lead times may vary.
- An MSN was shared on the 27th March 2020, please see attachment for further information.

Diclofenac/Misoprostol (Arthrotec 50) 50mg/200 microgram tablets

- Arthrotec 50 tablets are out of stock until early May 2020.
- Arthrotec 75 tablets remain available.

Fluoxetine 10mg tablets

- Fluoxetine 10mg tablets are out of stock until late 2020.
- Fluoxetine 10mg capsules and fluoxetine 20mg/5ml oral solution remain available.
- An MSN was issued on 12 March (attached) which provides further information.
- A serious shortage protocol (SSP) was issued on 12/3/2020. See link below:
<https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/serious-shortage-protocols-ssps>

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Levodopa/carbidopa/entacapone (Stanek) tablets - various strengths

- Teva have informed us of the following supply issues impacting Stanek tablets:

Stanek Presentation Affected	Out of Stock Date	Anticipated Resupply date
150mg/37.5mg/200mg tablets		
Pack size 100	19/02/2020	Mid-June 2020
Pack size 30	16/02/2020	Mid-June 2020
100mg/25mg/200mg tablets		
Pack size 30	25/02/2020	End June 2020
125mg/31.25mg/200mg tablets		
Pack size 100	24/04/2020	End July 2020
Pack size 30	27/03/2020	Mid-July 2020

- All other Stanek presentations remain available during this time.
- Supplies of Sastravi or Stalevo tablets, which are considered equivalent, continue to remain available. Please see MSN attached for further information.

Medroxyprogesterone (Provera) 400mg tablets

- Out of stock until mid-June 2020. All other strengths currently available.

Paracetamol tablets

- There has been a significant increase in demand over the recent weeks. DHSC is working with suppliers of paracetamol to monitor and assess available supplies and demand.
- DHSC are continuing to work suppliers to ensure further deliveries are made available and had received assurance about future deliveries expected imminently.

Promazine 25mg/50mg tablets

- Teva are out of stock until mid-April 2020
- Alternative preparations as advised in the MSN circulated on the 13 March (attached) are:
 - Promazine 25mg/5ml or 50mg/5ml oral syrup (licensed) OR;
 - Promazine 25mg & Promazine 50mg tablets (unlicensed imports)

Valproate semisodium (Depakote) 250mg/500mg tablets

- Depakote 250mg and 500mg tablets are out of stock until mid-April 2020 with ongoing limited supplies until July 2020.
- Limited supplies of Depakote tablets are available from parallel import companies (see information in MSN shared 28 February 2020, attached).
- Syonell (valproate semisodium) tablets are in stock and able to support the market during this time.
- Belvo (valproate semisodium) tablets are in stock and able to partially support this supply issue.
- NOTE: information in the MSN only applies to the use of valproate semisodium in licensed indications i.e. treatment of manic episode in bipolar disorder when lithium is contraindicated or not tolerated.

Others

Proctosedyl (cinchocaine 0.5%/hydrocortisone 0.5%) Ointment

- Out of stock until late May 2020. Proctosedyl suppositories remain available.

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Clenil Inhaler Range

- Chiesi have experienced large increases in demand on their inhaler range over the past two weeks.
- Chiesi are supplying product to wholesalers in line with historic demand to ensure stocks continue to remain available.
- Health care professionals and patients are reminded to only prescribe and order what they need during this time to ensure that all patients can continue to access their medicines.
- Chiesi have confirmed they have stock available of the following Clenil MDI inhalers and further deliveries are expected:
 - 50microgram
 - 200microgram
 - 250microgram
- Clenil 100microgram MDI inhalers have experienced a delay in their production due to an issue with the actuators for the device.
- Chiesi anticipate further stocks to become available towards the end of the w/c 30th March 2020.
- Alternative brands of beclomethasone inhaler remain available during this time.

Eye drops/treatments

Betamethasone (Vistamethasone) 0.1% eye drops

- Martindale are out of stock until October 2020.
- RPH Pharma have sufficient supply of Betnesol eye/ear 0.1% drops to support the market.

Fluocinolone Acetonide (Iluvien) 190 mcg Intravitreal implant in applicator

- Alimera Science are expected to be out of stock from the 17 March until mid- April 2020.
- Alternatives as advised by the Royal College of Ophthalmologists, remain available; dexamethasone (Ozurdex) 0.7mg intravitreal implant and triamcinolone acetonide (Kenalog) 40mg/ml Injection.

Ongoing Issues

Injectables

Adrenaline Auto-Injectors (AAIs)

- Recent supply issues affecting some brands of AAIs has impacted on all manufacturers, however, there are currently sufficient supplies overall to meet normal UK demand.

Emerade (Bausch & Lomb UK Ltd)

- On 28 November, the MHRA issued a Class 2 pharmacy level recall for all strengths of Emerade devices following reports from the manufacturer, Bausch & Lomb UK Limited, of Emerade devices that have failed to activate. See link:
<https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-emerade-150-300-and-500-microgram-solution-for-injection-in-pre-filled-syringe-mdr-57-08-19>
- On 29 November, DHSC issued a Supply Disruption Alert (SDA) with advice on how to manage patients affected. See link:
<https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102938>
- Subsequent to the pharmacy level recall above, on 4 March 2020, the MHRA issued a patient level recall for Emerade 150mcg devices:

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<https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-emerade-150-micrograms-solution-for-injection-in-pre-filled-syringe-pl-33616-0013-el-20-a-14>

- Patients and/or carers should return Emerade 150 micrograms auto-injectors to their local pharmacy once they have obtained a prescription for, and been supplied with, an alternative brand.
- Emerade 300 microgram and Emerade 500 microgram auto-injectors are not being recalled at present as there are insufficient supplies of alternatives to provide replacements.
- Patients currently holding Emerade 300mcg/500mcg devices are advised to continue to use the device(s) as instructed until the expiry date and to always carry two devices at all times.

Jext (ALK-Abello Ltd)

- Jext 150 microgram and 300mcg devices are currently available.
- Specific batches of UK licensed Jext 150 micrograms and 300 micrograms have received MHRA approval for extended use by four months beyond the labelled expiry date.
- Clinicians should check with patients requesting new Jext 150 micrograms and 300 micrograms to establish if they currently hold one of the batches that can be used beyond the listed expiry. If one of the listed batches is held, further supplies should be delayed until the extended expiry date, counselling the patient on the extended expiry.
- Please see the link for further information: <https://jext.co.uk/>

EpiPen/EpiPen Junior (Mylan)

- Prescription validation was lifted for EpiPen Junior devices on 10 February 2020.
- Supplies of EpiPen 300mcg remain available via a prescription validation process.
- Community Pharmacies can place orders for up to a maximum of two EpiPen's per prescription. Trusts place orders via Mylan's customer service team.
- Hospitals should request EpiPen's from the Mylan customer services team (mguk_customer.services@mylan.co.uk; +44 (0) 1707 853 100) with information including the number of the pens required, the reason for need and their Alliance Healthcare account number.
- Specific batches of EpiPen 300 micrograms have received MHRA approval for extended use by four months beyond the labelled expiry date.
- Clinicians should check with patients requesting new EpiPen 300 micrograms to establish if they currently hold one of the batches that can be used beyond the listed expiry. If one of the listed batches is held, further supplies should be delayed until the extended expiry date, counselling the patient on the extended expiry.
- Please see the link for further information: <http://www.epipen.co.uk/>

Adrenaline 1:1000 ampoules for anaphylaxis kits

- Adrenaline 1:1000 ampoules are currently available in sufficient quantities to meet normal demand.
- Some healthcare professionals may be holding an AAI 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.
- During the ongoing supply constraints, please use ampoules and not auto-injectors to replenish anaphylaxis kits. Remember to include the relevant dosing charts, syringes and needles.
- 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](#).

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Calcium Chloride 10% Pre-Filled Syringes

- Calcium chloride 10% (6.8mmol in 10ml) pre-filled syringes are out of stock until late April 2020.
- Calcium chloride 10mmol/10ml injection and 5mmol/5ml injection are currently in stock.
- A medicine supply notification has been shared with the NHS containing management advice and a UKMi memo is available at the following link: <https://www.sps.nhs.uk/articles/shortage-of-calcium-chloride-injection-10-millimoles-in-10-ml-and-5millimoles-in-5ml-ampoules/>
- Calcium gluconate 10% injection is available.

Crisantaspase (Erwinase) injection

- Porton Biopharma, the manufacturer of Erwinase, have had ongoing manufacturing issues affecting this product for the past 1-2 years with intermittent supply issues expected until mid-2020.
- Jazz Pharmaceuticals distributes Erwinase and supplies are currently available.
- Jazz Pharmaceuticals works closely with the clinical networks and supplies are prioritised on a patient need basis in conjunction with the treating clinicians.

Diamorphine 5mg and 10mg injection

- There are two suppliers of diamorphine hydrochloride 5mg and 10mg in the UK:
 - Accord are out of stock of 5mg and 10mg strengths, with a re-supply date of Summer 2020.
 - Wockhardt are out of 5mg and 10mg strengths with limited supplies expected to be available w/c 6th April 2020.
- The advice from both suppliers of diamorphine 5mg and 10mg strengths is that the supply will remain unpredictable for the foreseeable future.
- Diamorphine hydrochloride 30mg, 100mg, 500mg are available but manufacturers are unable to support an increase in demand on these strengths.
- Sufficient supplies of morphine sulfate 10mg/ml injection are available from Ethypharm and Hameln to support the diamorphine shortage. The Hameln presentation is preservative free.
- An updated supply disruption alert was issued 25th March. See the link below: <https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103005>

Epirubicin 10mg/50mg/100mg solution for injection

- There may be intermittent short-term supply issues until April 2020.
- A medicine supply notification has been shared with the NHS on 14 January (shared previously) which provides further information.

Midazolam 50mg/10ml solution for injection ampoules

- Hameln are currently out of stock until 3 April 2020.
- Accord are currently back in stock and supporting the market.
- Midazolam 10mg in 2ml ampoules remain available from both Hameln and Accord.
- Review local protocols, ensure that all those affected are aware of this issue and that consideration is given to mitigating the risks associated with switching to a different volume of midazolam (5mg/ml) ampoule presentation.
- A medicine supply notification has been shared with the NHS on 5 December (shared previously) which provides further information.

Mitomycin 2mg/10mg/20mg injection and mitomycin 40mg intravesical solution (Mitomycin-C)

- Kyowa Kirin are out of stock due to quality control release and manufacturing delays with no date for resupply.
- Please see the below links to the recent Supply Disruption Alerts (SDA) and an MHRA Class 2 recall for all unexpired Kyowa Kirin LTD Mitomycin-C products for further information:

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<https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102921>

MHRA Class 2 recall:

<https://www.cas.mhra.gov.uk/ViewAndAcknowledgment/viewAlert.aspx?AlertID=102920>

- Supplies of Medac mitomycin 40mg intravesical kits are available with more stock expected to be available in the coming months.
- Specialist importers can source unlicensed products. Lead times may vary.

Oily Phenol 5% (almond oil) injection

- Martindale, sole suppliers, are out of stock until August 2020.
- Specialist importers can source unlicensed products. Lead times may vary.

Procyclidine 10mg/2ml injection

- Accord, sole supplier, are out of stock until April 2020.
- Consider sharing remaining stock locally with the support of your regional procurement lead.
- Unlicensed imports of procyclidine are not available.
- An alternative injectable anticholinergic agent, benztropine mesilate (unlicensed), is available from pharmaceutical importers.
- A medicine supply notification has been shared with the NHS on 5 November (shared previously) which provides further information.

Somatropin (Genotropin) devices

- Pfizer are out of stock of 12mg refill cartridges, 12mg GoQuick and 0.6mg MiniQuick devices until late April 2020.
- Pfizer are out of stock of 0.8mg MiniQuick devices until late June 2020.
- Limited supplies of 5.3mg GoQuick and the following MiniQuick devices (1.0mg, 1.2mg, 1.4mg, 1.6mg, 1.8mg) are available until June 2020.
- For patients who are required to switch their device as a result of this issue, Pfizer will provide device training through your homecare provider at no cost to the Trust. If this is required, inform the homecare company of a change to prescription and the request for patient training. Alternatively, contact endocrinecare@pfizer.com for additional support.
- See the updated DHCP letter from Pfizer for further information (attached).

Tetracosactide 1mg depot injection

- Mallinckrodt, sole suppliers will be out of stock until the second half of 2020.
- Specialist importers can source unlicensed products. Lead times may vary.

Urokinase (Syner-KINASE) injection

- Syner-Med are currently in stock of all strengths of Syner-KINASE injection.
- Supply restrictions for the 10,000IU and 25,000IU will likely remain in place until late 2020.
- Details of suggested alternative products, if required, can be found in the UKMi memo 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/>
- Additional information for the product Taurolock has been shared previously. To place orders for this product, contact customerservice@kimal.co.uk and copy louise.kelly@kimal.co.uk

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Orals

Carbamazepine (Carbagen) various preparations

- Carbamazepine is considered a Category 1 anti-epileptic drug and patients should normally be maintained on the same brand, however Mylan (manufacturers of Carbagen) are out of stock of both carbagen 200mg and 400mg immediate and modified release tablets and unable to advise on a resupply date.
- Patients should have been switched to an alternative brand of carbamazepine tablets during this time.
- Novartis, an alternate manufacturer of carbamazepine (Brand: Tegretol) tablets are in stock of all presentations and are able to support additional demand.
- DHSC have worked with NHSE/I and UKMi to develop a clinical memo, which has been produced to support clinicians in prioritising and switching patients:
<https://www.sps.nhs.uk/articles/shortage-of-carbagen-carbamazepine-tablets/>

Clonidine 25microgram tablets

- Accord are out of stock and unable to advise a resupply date earlier than May 2020.
- Limited supplies are currently available from Sandoz. Further supplies are due at the end of April.
- However, where supplies may be limited please refer to the medicine supply notification that has been shared with the NHS on 20th December (shared previously).
- The clinical memo from UK Medicines Information (UKMi) has been published on the SPS website:
<https://www.sps.nhs.uk/articles/shortage-of-clonidine-25microgram-tablets/>

Co-careldopa 25mg/100mg tablets

- Teva, a generic supplier is out of stock and is currently unable to provide a resupply date.
- MSD, the supplier of the brand *Sinemet Plus* can cover supply for the whole market during this time.

Co-fluampicil 250mg/250mg capsules

- Crescent are experiencing a long term out of stock.
- Clinicians are advised to prescribe flucloxacillin and ampicillin capsules as separate preparations, considering patients' ability to swallow an increased number of capsules.
- Ampicillin 250mg and 500mg capsules are available from Crescent and Chemidex.
- Ampicillin oral suspensions (125mg/5ml and 250mg/5ml) are also available from Chemidex.

Colestipol (Colestid) plain/orange 5g granules

- Colestid sachets are out of stock until mid-April followed by intermittent limited supplies until July 2020.
- For further information on alternative bile-acid sequestrants, see the UKMi memo:
<https://www.sps.nhs.uk/articles/shortage-of-bile-acid-sequestrants/>

Colestyramine (Questran) Powder for Oral Suspension

- Cheplapharm are out of stock of Questran Powder 4g sachets until 2021.
- Specialist importers can source unlicensed products. Lead times may vary.
- Limited supplies of Questran Light are currently available through Alliance Healthcare.
- Mylan have recently launched a generic colestyramine 4g light sachet which is available in wholesalers.

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Contraceptive products

Noriday (norethisterone) 350 micrograms tablet

- Pfizer are out of stock until w/c 6 April 2020.
- 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 are out of stock and are unable to provide a resupply date.
- 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>

Zoely (estradiol/nomegestrol) 2.5mg/1.5mg tablets

- MSD are out of stock due to manufacturing constraints and currently advise a resupply date of 2022.
- UKMi have advised that there are no exact equivalent preparations to Zoely available in the UK market
- Clinicians are advised to refer to CKS guidance for advice COCs:
<https://cks.nice.org.uk/contraception-combined-hormonal-methods>

Disopyramide 150mg capsules

- Mylan, sole supplier is out of stock until late April 2020.
- Specialist importers can source unlicensed products. Lead times may vary.
- Disopyramide 100mg capsules are available.
- See link below for the Supply Disruption Alert issued 14 June 2019:
<https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102869>
- A medicine supply notification has been shared with the NHS on 15 November (shared previously) which provides further information.

Fluoxetine 20mg dispersible tablets (Olena)

- Currently out of stock until end of April 2020.
- An oral solution, fluoxetine 20mg/5ml, is available from alternative manufacturers.

Galantamine 8mg/12mg tablets

- Teva will be out of stock of their immediate release galantamine preparations (8mg and 12mg) until July 2020.
- Galantamine modified release capsules (8mg, 16mg, 24mg) and galantamine 4mg/ml oral solution are available.
- UKMi guidance for switching preparations below:
 - 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.

Histamine (H2) antagonists

- Famotidine: 20mg and 40mg tablets are out of stock until April 2020.

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- Cimetidine: 200mg, 400mg and 800mg tablets from Ennogen are out of stock until 30 March 2020. Medreich are currently out stock of 400mg tablets until August 2020. Rosemont are currently in stock of 200mg in 5ml oral solution.
- Nizatidine: 150mg and 300mg tablets are out of stock. Medreich and Mylan have long term manufacturing issues with no confirmed resupply date.
- A medicine supply notification has been shared with the NHS on 20 December 2019 (shared previously) which provides further information. An updated MSN summary table of expected resupply dates was shared 27 March 2020.

Hormone Replacement Therapy products (HRT)

There are still some ongoing supply issues, please see **Table 2** in the Appendix for a full update on the availability of all HRT products.

Elleste oral HRT Range

- Mylan, sole supplier of the Elleste range, are out of stock due to manufacturing issues at their contract manufacturing site. Resupply is expected in late 2020.
- See **Table 1** below for equivalent alternatives to the Elleste range.

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	Out of stock	Progynova 1mg	estradiol hemihydrate	In stock
			Zumenon 1mg		In stock
Elleste Solo 2mg	estradiol hemihydrate	Out of stock	Progynova 2mg	estradiol hemihydrate	In stock
			Zumenon 2mg		In stock
Elleste Duet Conti	estradiol 2mg/ norethisterone 1mg	Out of stock	Kliofem	estradiol 2mg/ norethisterone 1mg	In stock
Elleste Duet 1mg	estradiol 1mg/ norethisterone 1mg	Out of stock	NovoFem	estradiol 1mg/ norethisterone 1mg	In stock

Ethinylestradiol 10microgram/50microgram tablets

- UCB, sole supplier is out of stock due to manufacturing issues and currently unable to advise a resupply date.
- Specialist importers can source unlicensed products. Lead times may vary.

Evorel transdermal patch range

- On 24 October 2019, Janssen-Cilag divested the Evorel range (Evorel, Evorel Conti and Evorel Sequi) to Theramex UK Ltd.
- Evorel 50 and Conti are back in stock. Resupply of Evorel 25, 75, 100 is expected early April 2020.
- A copy of an updated UK stock update issued by Theramex is attached.
- UKMi have published guidance to advise on suitable alternatives:
<https://www.sps.nhs.uk/articles/shortage-of-evorel-hormone-replacement-therapy-hrt-patch-range/>
- The British Menopausal Society with the support of the Royal College of Obstetrics and Gynaecologists have published a document advising on HRT preparations and equivalent alternatives, to aid prescribing during this period: <https://thebms.org.uk/2019/11/british-menopause-society-further-update-on-hrt-supply-shortages-26-november-2019/>

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- Specialist importers can source unlicensed products. Lead times may vary.

FemSeven Transdermal patch range

- Teva divested the FemSeven product range to Theramex UK Ltd mid-2018.
- Theramex have confirmed that whilst new manufacturing arrangements are being established, the FemSeven range will be out of stock until end of 2020.
- Specialist importers can source unlicensed products. Lead times may vary.

Levofloxacin 250mg & 500mg tablets

- Accord are out of stock of levofloxacin 250mg tablets until April 2020
- Levofloxacin 500mg tablets are also out of stock. Accord are expecting resupplies from June 2020 and Teva have been unable to confirm resupply date.
- Specialist importers can source unlicensed products, lead times vary.

Methadone (Physeptone) 1mg/ml sugar free oral solution

- Martindale are out of stock of Physeptone 1mg/ml sugar free oral solution (100ml) until April 2020.
- All other methadone preparations and pack sizes remain available.

Metoprolol 50mg and 100mg tablets

- Aurobindo-Milpharm, the sole supplier in the UK, have a long-term shortage affecting metoprolol 50mg and 100mg tablets; caused by some manufacturers discontinuing the products and others having supply difficulties.
- They currently have limited stock available; supply is likely to be intermittent for several months.
- See the link below for a UKMi memo which advises on management options:
<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.

Mianserin 10mg and 30mg tablets

- Mylan, sole supplier is out of stock of both strengths until June 2020.
- Specialist importers can source unlicensed products. Lead times may vary.
- For patients where imports are not appropriate, see previous updates for clinical advice.

Moclobemide 150mg and 300mg tablets

- Mylan (Manerix®) are expecting resupply of both strengths by end of April 2020.
- Sandoz-GB currently expect resupply for the 150mg in July 2021 and the 300mg in March 2021.
- Specialist importers can source unlicensed products. Lead times may vary.

Nifedipine (Adalat) tablets

- There are ongoing supply issues with the Adalat Retard and LA range from Bayer. Alternative nifedipine presentations continue to remain available from generic suppliers.
- Supplies of nifedipine 5mg and 10mg immediate release soft gel capsules are now available from Relonchem.
- Please refer to the letter (shared previously) from Bayer and the shortages memo from UKMI:
<https://www.sps.nhs.uk/articles/shortage-of-adalat-nifedipine/>

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Penicillamine 125mg tablets

- Penicillamine 125mg tablets are out of stock until mid-April 2020.
- Specialist importers can source unlicensed products. Lead times may vary.
- Penicillamine 250mg tablets are currently available.
- A medicine supply notification has been shared with the NHS on 20 February (shared previously).

Pethidine 50mg tablets

- Martindale are out of stock until July 2020.
- Teva can support the full market until Martindale's resupply.

Phenelzine sulfate (Nardil) 15mg tablets

- Kyowa Kirin, sole supplier is out of stock due to manufacturing delays and is currently unable to advise a resupply date.
- Specialist importers can source unlicensed products. Lead times may vary - contact Clinigen, Target, Alium, Mawdsleys, Durbin, WEP Clinical and Waymade for further information.
- Unlicensed imports can be obtained through normal wholesaler routes. If unable to obtain through wholesalers, pharmacists are advised to contact the relevant specialist importers directly.
- UKMi 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/>

Phenytoin (Epanutin) 50mg Chewable Infatabs

- Pfizer are out of stock until mid-2020 due to a manufacturing delay.
- Pfizer has obtained approval from the MHRA to import stock of Dilantin (phenytoin) Infatabs from Canada.
- Canadian packs of Dilantin are considered unlicensed in the UK.
- A copy of the DHCP letter has been shared previously.

Phenytoin (Epanutin) 30mg/5ml oral suspension

- Pfizer will be out of stock of Epanutin oral suspension until late June 2020.
- The Canadian brand of phenytoin 30mg/5ml oral suspension - 'Dilantin-30' - is equivalent to Epanutin 30mg/5ml oral suspension and supplies are available on an 'unlicensed' basis via Pfizer customer contact centre on 0845 608 8866.
- Different formulations of phenytoin (other than Dilantin 30mg/5ml oral suspension) are not interchangeable and if patients are switched to anything other than 'Dilantin (phenytoin) 30mg/5ml oral suspension' careful management of switching and monitoring is required which may require specialist advice, support, or referral.
- Please find attached a DHCP letter for further information.
- A supply disruption alert was issued 25 February. See the link below for further information: <https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102983>

Phenytoin 100mg capsules

- Accord are expected to be out of stock of phenytoin 100mg capsules until early May 2020 due to a regulatory change at their manufacturing site.
- Flynn Pharma can support the full market during this time.
- As phenytoin is classed as a Category 1 anti-epileptic drug by the MHRA, switching to an alternative formulation requires monitoring and may also require specialist support, advice or referral.
- Please see the below link to the recent Supply Disruption Alert (SDA) issued on 10 January: <https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102954>

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Prazosin (Hypovase) 500mcg/1mg tablets

- Limited supplies of Hypovase 500mcg and 1mg tablets are currently available. Resupply expected to be June 2020.

Quinapril 10mg/hydrochlorothiazide 12.5mg (Accuretic) tablets

- Pfizer are currently out of stock until w/c 6 April 2020.
- There are several alternative combination preparations of ACE-Inhibitors with diuretics and UKMi have advised that patients can be safely switched, with clinical supervision.
- Specialist importers can source unlicensed products. Lead times may vary.

Ranitidine (all preparations)

- Ranitidine tablets, effervescent tablets and oral solution are expected to be out of stock until further notice due to global regulatory investigations.
- An updated supply disruption alert with additional guidance on clinical alternatives in paediatrics was issued on 20 December 2019 and is available at [SDA/2019/005-U2](#)
- Ranitidine injection 50mg/2ml solution for injection is expected to be out of stock from the end of May 2020, until further notice due to global regulatory investigations.
- A medicine shortage notification will be circulated shortly.

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 supplies are available.
- Specialist importers can source unlicensed products. Lead times may vary.

Tuberculosis medications

- See the table below for a summary of the supply position with tuberculosis medications.
- A medicine supply notification has been shared with the NHS on 23rd March (attached) which provides further information.

Product	Supplier	Current stock position	Anticipated re-supply date	Suggested management plan
Rifampicin 150mg capsules	Sanofi	In stock		n/a
	DE Pharmaceuticals	In stock		
	Mylan	In stock		
Rifampicin 300mg capsules	Sanofi	In stock		n/a
	Sandoz	In stock		
	Mylan	In stock		
	DE Pharmaceuticals	In stock		
	DrugsRUs	Out of stock		

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Rifampicin 100mg/5ml syrup	Sanofi	In stock		n/a
Ethambutol 100mg tablets	Morningside	In stock		Purchase off contract if required to ensure continuity of care for patients.
	Thornton & Ross	In stock		
	Kent	In stock		
	DE Pharmaceuticals	In stock		
	Intrapharm	Out of stock	Late March	
Ethambutol 400mg tablets	Kent	In stock		Purchase off contract if required to ensure continuity of care for patients.
	Thornton & Ross	In stock		
	Intrapharm	Limited stock	Late March	
	Morningside	In stock		
Pyrazinamide 500mg tablets	Thornton & Ross	In stock		n/a
	Macleod's	In stock		
	Morningside	In stock		
Isoniazid 50mg tablets	RPH Pharmaceuticals	In stock		n/a
Isoniazid 100mg tablets	Morningside	In stock		n/a
	RPH Pharmaceuticals	In stock		n/a
Rifinah 150 tablets (rifampicin 150mg/isoniazid 100mg)	Sanofi	In stock		n/a
Rifinah 300 tablets (rifampicin 300mg/isoniazid 150mg)	Sanofi	In stock		Purchase off contract if required to ensure continuity of care for patients.
	DrugsRUs	Limited stock	TBC	
Rifater tablets (rifampicin 120mg/pyrazinamide 300mg/isoniazid 50mg)	Sanofi	Out of stock	Mid-April	Prescribe/dispense as individual ingredients or place orders for imports. Importer companies have indicated that unlicensed imports can be sourced, lead times vary.
	DrugsRUs (Parallel Import)	Out of stock	TBC	
Voractiv (Rimstar) tablets	Thornton & Ross	Out of stock	mid-April 2020	Prescribe/dispense as individual ingredients or place orders for imports. Importer companies have indicated that unlicensed imports can be sourced, lead times vary. Do not use Rifater or Rifinah

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				products as these presentations cannot meet an increase in demand.
Cycloserine 250mg capsules	King Pharmaceutical s	Out of stock	TBC	Place orders for imports. Importer companies have indicated that unlicensed imports can be sourced, lead times vary.

Valproic acid (Convulex) 500mg capsules

- Convulex 300mg capsules are out of stock with no resupply date confirmed.
- Supplies of Convulex 150mg and 500mg capsules are currently available.
- Please see the below link to the recent Supply Disruption Alert (SDA) issued on 23 December 2019:
<https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102953>

Others

Fentanyl (Instanyl) 50mcg nasal spray

- Takeda are out of stock of Instanyl 50mcg nasal spray until May 2020.
- Instanyl 100mcg and 200mcg nasal sprays 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.
- UKMi memo on management options below:
<https://www.sps.nhs.uk/articles/shortage-of-actiq-lozenges-and-instanyl-nasal-spray-immediate-release-fentanyl-citrate/>

Fludrocortide 0.0125% cream and ointment

- Typharm Limited cannot release further stock of fludrocortide cream and ointment due to updates to their licences and changes to regulatory standards.
- There is no confirmed resupply date.
- Fludrocortide 4micrograms/cm² tape remains available.

Mesalazine (Salofalk)1g suppositories

- Salofalk 1g suppositories are out of stock until late July 2020.
- Salofalk 500mg suppositories are currently available.
- Pentasa 1g suppositories remain available.
- UKMi memo on management options below:
<https://www.sps.nhs.uk/articles/shortage-of-salofalk-mesalazine-suppositories-500mg-and-1g/>
- A medicine supply notification has been shared with the NHS on 1 November (shared previously) which provides further information.

Eye drops/treatments

Cyclopentolate hydrochloride 1% Minims (Bausch and Lomb)

- Limited supplies of cyclopentolate 1% minims until early April 2020.
- Cyclopentolate 0.5% minims are currently available.

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- A Medicines Supply Notification was shared with the NHS (shared previously) on 20 December 2019, which provides further information.
- Preservative containing supplies of cyclopentolate hydrochloride 0.5% and 1% eye drops (Mydrilate) remain available.
- Specialist importers can source unlicensed cyclopentolate 1% minims. Lead times may vary.

Mydrane 0.2mg/ml + 3.1 mg/ml + 10 mg/ml solution for injection

- Limited supplies until April 2020.
- Phenylephrine Minims and Mydriastert are currently available.

Sofradex ear/eye drops

- Sanofi are out of stock until September 2020.
- Alternative preparations for use in the ear/eye remain available.

Vaccines

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

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

Combined hepatitis A & B (Twinrix)

- Limited supplies of Twinrix Adult singles and packs of 10 are currently available.
- Twinrix paediatric and Ambrix remain available.
- Monovalent hepatitis A and hepatitis B vaccines also remain available.

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.msd-uk.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.

Measles, Mumps and Rubella (MMR) vaccine

- Limited supplies MMRVAXPRO (MSD) are available for the private market (locally procured stock) until the end of March 2020 respectively due to global increase in demand. GSKs Priorix is available.
- This supply issue does not impact the nationally procured MMR vaccine used for the Public Health England's (PHE) national programme.
- Most of the MMR vaccinations provided in the UK are nationally procured by PHE and delivered as part of a national immunisation programme.

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Pneumococcal Polysaccharide Vaccine 23-valent vaccine (PPV23) vials and Pneumovax 23 pre-filled syringes

- MSD, sole supplier of PPV23 vaccine, are currently out of stock of Pneumovax pre-filled syringes and have limited supplies of PPV23 vials. Resupply is expected by May and early May 2020, respectively.
- Public Health England (PHE) have issued guidance on how available supplies should be managed at this time. This guidance advises the need for the prioritisation of patients considered to be in the high priority clinical risk group. Find full guidance on PHE's Vaccine Update Issue 300 (page 12): https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/844742/PHE_11388_vaccine_update_300_bug_special_october2019ppv.pdf

Discontinuations

Almogran (almotriptan) 12.5mg tablets (Almirall)

- Almogran tablets have been discontinued with immediate effect.
- Generic almotriptan 12.5mg tablets remain available from other suppliers.

Citalopram 10mg, 20mg and 40mg tablets (Mylan)

- Mylan plans to discontinue citalopram 10mg, 20mg and 40mg tablets with immediate effect.
- Citalopram tablets remain available from a number of generic suppliers.

Fluconazole 50mg capsules (Teva)

- Fluconazole 50mg capsules have been discontinued with immediate effect.
- Fluconazole 50mg capsules remain available from a number of other generic suppliers.

Fluconazole 2mg/ml IV (Teva)

- Fluconazole 2mg/ml (50mg, 100mg & 200mg) solution for infusion vials have been discontinued with immediate effect.
- Fluconazole IV remains available from a number of other generic suppliers.

Sporanox IV 10 mg/ml concentrate and solvent for solution for infusion (Janssen-Cilag)

- Janssen plans to discontinue Sporanox (itraconazole) IV from the UK market in October 2020.
- Itraconazole injection remains available from other generic suppliers.

Resolved (date resolved)

Amiloride 5mg tablets (28/02/20)

Aztreonam (Azactam) 1g injection (10/3/20)

Adcal D3 dissolve 1500mg/400IU effervescent tablets (1/4/20)

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Cyclopentolate hydrochloride 0.5% Minims (03/20)
Diazepam 2mg/5ml oral solution (17/3/20)
Indivina HRT range (1mg/5mg, 2mg/5mg, 1mg/2.5mg) (23/03/20)
Lorazepam (Ativan) 4mg/ml injection (23/3/20)
Mesalazine (Salofalk) 500mg suppositories (23/3/20)
Opicapone (Ongentys) 50mg capsules (02/03/20)
Paroxetine (Seroxat) 10mg/5ml oral solution (10/03/20)
Penicillamine 250mg tablets (28/2/20)
Salbutamol (Ventolin) 2mg/5ml Syrup (03/03/20)
Sayana Press (medroxyprogesterone acetate) 104mg injection (4/3/20)
Sodium thiosulfate 12.5g/50ml solution for injection vials (16/03/20)
Somatropin (Genotropin) 5.3mg refill cartridges (28/2/20)
Valproic acid (Convulex) 150mg/500mg capsules (31/3/20)
Vecuronium 10mg powder for solution for injection (Ranbaxy) (02/03/20)
Verapamil (Securon) 5mg/2ml injection (26/3/20)

Appendix

Table 2: HRT availability and anticipated resolution dates

		Oestrogen Only			
Ingredient (s)	Manufacturer	Brand	Strength	Current Availability	Anticipated resupply date
		Oral preparations			
Estradiol hemihydrate	Mylan	Elleste Solo	1mg	OOS	End of 2020
			2mg	OOS	
	Mylan	Zumenon	1mg	In stock	
			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	
			625mcg	In stock	
			1.25mg	In stock	
Ethinylestradiol	UCB pharma Ltd.	Ethinylestradiol	10mcg	OOS	Resupply date unavailable. Unlicensed imports available; lead times vary
			50mcg	OOS	
			1mg	In stock	
Transdermal patches					
Estradiol	New owner: <u>Theramex</u>	Evorel	25 mcg	OOS	By the mid-April 2020. Unlicensed imports available; lead times vary
			50mcg	In Stock	
			75mcg	OOS	
			100mcg	OOS	
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	Long term OOS	End of 2020 Unlicensed imports available; lead times vary
			75mcg		
			100mcg	Long term OOS	
	Bayer	Progynova TS	50mcg	In stock	
			100mcg	In stock	
Mylan	Elleste Solo MX	40mcg	In stock		
		80mcg	In stock		
Topical (Transdermal gels/creams/other delivery systems)					

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Estradiol	Besins Healthcare (UK) Ltd	Oestrogel	0.06%	In stock	
Estradiol hemihydrate	Orion	Sandrena	0.5mg	In stock	
			1mg (28)	In stock	
			1mg (91)	In stock	
	Pfizer	E-string 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	OOS	Mid to end of 2020
	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	In stock	
			1mg/5mg	In stock	
low dose conjugated oestrogen/medroxyprogesterone	Pfizer	Premique	300mcg/1.5mg	In stock	
Transdermal patch					
Estradiol hemihydrate/ norethisterone acetate	New Owner: <u>Theramex</u>	Evorel Conti	3.2mg/11.2mg	In stock	
Estradiol hemihydrate/ levonorgestrel	Theramex	FemSeven Conti	1.5mg/ 0.525mg	Long term OOS	End of 2020

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Sequential combined therapy					
Oral preparations					
Estradiol [X,X] / norethisterone acetate	Resource Medical UK	Clinorette	[2mg, 2mg]/ 1mg	Long term OOS	
Estradiol/norgestrel	Mylan	Cyclo-progynova	2mg/500mc g	Long term OOS	
Estradiol hemihydrate / norethisterone acetate		Elleste Duet	1mg/ 1mg	OOS	End of 2020.
Estradiol hemihydrate/ dydrogesterone			2mg/ 1mg	OOS	
Estradiol hemihydrate / norethisterone acetate		Novo Nordisk	Novofem	1mg/ 1mg	In stock
	Trisequens			[2mg, 2mg, 1mg]/ 1mg	In stock
Estradiol valerate/ medroxyprogesterone acetate	Orion	Tridestra	2mg/20mg	In stock	
Transdermal patch					
a) Estradiol hemihydrate and b) estradiol hemihydrate/ norethisterone acetate	New Owner: <u>Theramex</u>	Evorel Sequi	a)3.2mg b) 3.2 mg /11.2 mg	OOS	May 2020.
a) 1.5mg of estradiol hemihydrate b) Estradiol hemihydrate /levonorgestrel	Theramex	FemSeven Sequi	a) 1.5mg b) 1.5mg /1.5mg	Long term OOS	End of 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	