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## Supply Issues Update for Primary and Secondary Care: July 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 as it may be commercially sensitive; 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 08 July 2019

### New Issues

#### Injectables

##### Aciclovir 500mg/20mL and 1g/40mL injection

- Several suppliers are currently experiencing issues with availability of aciclovir injection.
- Sufficient stock is available at wholesalers; however, Trusts may need to switch from aciclovir solution to powder and from 500mg and 1g vials to 250mg vials.

##### 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).

##### Marcaïn Heavy (bupivacaine hydrochloride anhydrous) 0.5% injection

- Aspen the sole UK supplier of Marcaïn Heavy are currently out of stock due to manufacturing issues.
- Further stock is currently expected to be available by 22<sup>nd</sup> July 2019, however we are working with Aspen to try and expedite this date.
- In light of the critical supply situation, we have been working with NHS England, the Royal College of Anaesthetists (RCOA) and the Association of Anaesthetists and have issued a supply disruption alert (SDA) today, which can be found at the link below:  
<https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102875>
- We have been working closely with Aspen who have obtained approval from the MHRA to import a limited amount of unlicensed stock from the Swedish and Danish market, which should be available next week.
- In addition, some of the specialist importer companies have identified stock from other European countries that they are importing as an unlicensed product and should be available for hospitals to order.

#### **The CAS alert contains the following local actions to be undertaken urgently:**

- Centralise stock of Marcaïn Heavy 0.5% (bupivacaine hydrochloride anhydrous) solution for injection from all clinical areas except obstetrics with support from pharmacy.
- Local decisions should be made about which clinical areas/specialties can safely use alternatives to Marcaïn Heavy 0.5% (bupivacaine hydrochloride anhydrous) solution for injection on a temporary basis. Other bupivacaine injectable preparations continue to remain available during this time.
- Existing supplies of Marcaïn Heavy 0.5% (bupivacaine hydrochloride anhydrous) solution for injection should be reserved for clinical areas, particularly obstetrics, that cannot safely use an alternative agent, especially in emergency situations.
- NHS Trusts who have excess stock are encouraged to share stock with other local hospitals whose immediate needs may be greater.

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- Following centralisation of stock, if any NHS Trust does not have enough Marcain Heavy 0.5% (bupivacaine hydrochloride anhydrous) solution for injection stock to support local use they should place orders for unlicensed supplies, limited amounts of which are available.
- Following this management plan, please can we ask that hospitals who still find themselves in a critical supply situation make their regional procurement specialists aware, so they can feedback to DHSC.

## Orals

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

- GSK the sole supplier of cefuroxime 125mg/5ml suspension will be out of stock until mid-August 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.

### Disopyramide 100mg tablets

- All UK suppliers of disopyramide 100mg tablets are out of stock. Sanofi has a resupply date of mid-August and Mylan now has a resupply date of early August.
- 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>

### Indivina (Estradiol/ Medroxyprogesterone) 2mg/5mg tablets (please also see HRT products section page 14)

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

### Joyrides (Hyoscine Hydrobromide 150 microgram Tablets)

- Teva have a manufacturing issue and are currently out of stock of Joyrides until August 2019.
- Bayer also supply this product (Kwells Kids) and are in stock.

### Noriday

(please also see OCP products section page 15)

- Pfizer, the supplier of the oral contraceptive pill (OCP), Noriday, have advised that due to a delay at the manufacturing site, it will be out of stock until the end of July.
- 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:>

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Norimin (ethinylestradiol/norethisterone) 0.035mg/1mg tablets  
(please also see OCP products section page 15)

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

Salbutamol 2mg/5ml syrup

- Both suppliers of salbutamol 2mg/5mL syrup, GSK and Pinewood, are currently out of stock of Salbutamol 2mg/5ml syrup.
- GSK, (Ventolin) have advised a resupply date of early August 2019.
- Pinewood are currently unable to advise a resupply date.
- Specialist importers have identified unlicensed stock of salbutamol 2mg/5ml syrup they can bring into the UK from abroad. However, please note lead times for these products vary.
- Salbutamol 2mg and 4mg tablets are also available from Accord UK.
- UKMI have prepared the following clinical memo, which is available on the SPS website:  
<https://www.sps.nhs.uk/articles/shortage-of-salbutamol-syrup-2mg-5ml/>

## Others

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 are five days.
- BOC have produced the attached Dear HCP letter in relation to this issue.
- If Trusts are having difficulty obtaining stock they are advised to contact their local BOC account managers.

Prostin E2 (dinoprostone) 3mg Vaginal Tablet

- Pfizer are out of stock of Prostin E2 vaginal tablets until mid-August.
- Below are the medicinal products and devices that may be considered alternatives to the dinoprostone 3mg vaginal tablet and a summary of their availability:

Product (brand)	MAH	Availability	Notes
<b>Significant support available</b>			
Dinoprostone (Prostin E2) 1mg vaginal gel	Pfizer	Able to support vaginal tablet shortage	Not bioequivalent to vaginal tablet, please refer to SPC for further detail and see Pfizer comparison summary (attached)

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Dinoprostone (Prostin E2) 2mg vaginal gel	Pfizer	Able to support vaginal tablet shortage	Not bioequivalent to vaginal tablet, please refer to SPC for further detail and see Pfizer comparison summary (attached)
Imported Dinoprostone (Prostin E2) 3mg vaginal tablet	Unlicensed import	Good availability, currently approximately 40-60% of usage. Ordering imports may stimulate importers to source further stock from other markets.	Further information will be circulated from regional procurement leads. Please note lead times are approximately 2 weeks.
<b>Limited support available</b>			
COOK Cervical Ripening Balloon	Cook Medical	Can make additional stock available to cover 10-25% of usage.	Consider training requirement if Trust has no experience of using this product. Please contact Cook Medical (detail below) for further information and support with training as well as to inform them of your preference for their product and the likely quantities required. Leisl de Lafontaine, Senior Area Manager, COOK Medical <a href="tel:+447766426154">+44 7766 426154</a> <a href="tel:+442073654183">+44 207 365 4183</a> <a href="mailto:leisl.delafontaine@cookmedical.com">leisl.delafontaine@cookmedical.com</a>
<b>Not able to support market – do NOT order above forecasted demand</b>			
Dinoprostone (Propess) 10mg vaginal delivery system	Ferring	Not able to support uplift in demand	Unable to uplift volumes due to long lead times and storage requirements. Any ordering in excess of forecasted demand could precipitate an out of stock on this line.
Misoprostol (Mysodelle) 200mcg vaginal delivery system	Ferring	Not able to support uplift in demand	Unable to uplift volumes due to long lead times and storage requirements. Any ordering in excess of forecasted demand could precipitate an out of stock on this line.

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### Skinoren (azelaic acid) 20% cream

- Bayer, sole suppliers, are out of stock of Skinoren 20% cream with resupply expected in mid-October 2019. The license will be transferred to Leo Pharma from 1st July 2019.
- 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 retinoids are 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>

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

- Sanofi, the sole supplier of Tilade inhaler, are currently out of stock until mid-August.
- UKMI have advised that Intal (Sodium Cromoglicate-5mg/dose) is interchangeable and 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>

## Ongoing Issues

### Injectables

#### Ancotil (flucytosine) injection

- Mylan, the sole supplier of flucytosine, have experienced a manufacturing delay with this product.
- They are currently out of stock; further stock is expected in July 2019.
- There is stock availability within the NHS and information has been shared with regional procurement specialists to request they facilitate sharing between Trusts if stock is required urgently for a patient.
- Specialist importers have confirmed that they have sourced unlicensed stock and some specialist importers currently have stock available.

#### 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.

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- Further supplies of diamorphine 5mg injection are expected w/c 5<sup>th</sup> August 2019. All other strengths of diamorphine injection are available.
- 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).

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

- There is sufficient diamorphine 10mg injection to support forecasted use of diamorphine 5mg injection. Diamorphine will be available to order from usual wholesalers.

### ***Recommended Local Action for Primary Care:***

- Please share this information with relevant networks locally including GP practices, community pharmacies and substance misuse networks.
- Prescribers should be made aware that only diamorphine 10mg ampoules will be available during this period and ensure that prescriptions specify this preparation. Prescribers should take extra care when calculating the dose to be administered.
- Locally, health care professionals should follow local controlled drug policies for the safe management and disposal of excess waste of diamorphine during this time and should ensure that:
  - Any wastage should be rendered irretrievable and must be disposed of.
  - Clear records should be kept of what was administered, and what was discarded and should be witnessed wherever possible.
  - Please work with your Controlled Drug Accountable Officer where necessary.

### **Secondary care NHS trusts in UK**

- 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.
- Other opioids are available to support this supply issue but should only be used following approval by regional procurement lead.
- The following UKMI clinical memo has been developed to support with the use of alternatives: <https://www.sps.nhs.uk/articles/shortage-of-diamorphine-5mg/provides-more-information-about-the-alternatives-to-diamorphine-the-first-line-agent-being-morphine-injection>.

### ***Recommended Local Action for secondary care:***

- Discuss this supply issue with clinical colleagues and review and share UKMI guidance.
- Do not consider using other presentations of diamorphine to cover shortfall as there are insufficient stocks to support this supply issue.
- Consider reserving available supplies of diamorphine 10mg injection for priority areas.
- Morphine 10mg injection (Hameln) will be available to cover the diamorphine 5mg injection shortfall and should be considered first line. Continue to order morphine 10mg injection from Martindale in line with historic demand. Martindale CANNOT support increased orders.
- Please only order to cover existing demand and shortfall. Do not stock pile as this will lead to issues with other Trusts accessing stock. Please consider how you will manage having two morphine 10mg injection presentations in your departments.
- Please let your regional procurement specialist know of any local issues or if you are considering using an alternative other than morphine.



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- If your Trust supports any local hospices with diamorphine injection, please discuss with your regional procurement lead who will review your allocation.

EpiPen and EpiPen Junior

- The supply situation for EpiPen and EpiPen Junior continues to improve, and further stock is due in the coming months.
- All preparations of EpiPen, Emerade and Jext adult and junior are currently available via wholesalers.
- 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/>

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 become available w/c 15<sup>th</sup> July 2019.
- There are likely to ongoing intermittent supply issues 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.

Fludarabine 50mg/2ml injection

- Teva have a supply issue with fludarabine solution for injection and expect to have limited supplies until the next delivery in August due to API issues.
- Latest updates from Accord:
  - The 50mg/2ml solution for injection - limited supplies available through AAH and Alliance
  - The 50mg powder - limited supplies available through AAH and Alliance
- Sanofi have limited stock of the 50mg powder presentation (Fludara) and are not able to support any increase in demand.
- Specialist importers can source unlicensed fludarabine injection with variable lead times. Please contact your regional procurement leads for further information.

Gadovist preparations

- Manufacturing issues at Bayers' Berlin site is affecting supplies of Gadovist. This issue is likely to go on for several months.
- We have engaged with Bracco and Guerbet regarding their supply position on other gadolinium containing products. Both companies have good supplies available and have enough 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 PFS	Currently <b>OOS</b> until the next delivery that is scheduled to arrive in July*.
Bayer Plc	Gadovist 1mmol/ml solution for injection 15ml vials	Currently <b>in-stock</b> . It is anticipated that current stock levels will be sufficient until the first week of July,

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		followed by a short <b>OOS</b> period until the next planned delivery at the end of July*.
Bayer Plc	Gadovist 1mmol/ml solution for injection 5ml PFS	Currently <b>OOS</b> until the mid-August*.
Bayer Plc	Gadovist 1mmol/ml solution for injection 7.5ml PFS	Currently <b>OOS</b> . The next delivery is scheduled for mid-August*.
Bayer Plc	Magnevist 2mmol/l solution for injection 20 ml PFS	Currently <b>OOS</b> . Next delivery is due early-July. However, anticipated stock quantities lead to the expectation that each delivery will be consumed by back-orders. Therefore, supply will continue to be significantly interrupted/reduced until at least Q3 2019.
Guerbet UK	Dotarem 5ml vial; 10ml vial; 10ml PFS; 15ml vial; 15ml PFS; 20ml vial; 20ml PFS	All presentations in stock and Guerbet have enough stock to support the shortage
Bracco UK Ltd	ProHance 0.5mmol/ml 10ml PFS; 10ml vial; 15ml via; 17ml PFS; 20ml vial	All presentations in stock and Bracco have enough stock to support the shortage

\* Overall, it is anticipated that restricted supply will be likely to continue through Q3/Q4 2019, due to production problems.

#### Idarubicin 5mg injection

- Pfizer are out of stock of idarubicin 5mg injection due to a quality issue.
- We have been working with the importers who have confirmed that limited supplies are available from Europe and USA – hospitals requiring stock should place orders NOW for unlicensed imports as lead times will vary.
- Hospitals who have surplus stock have been asked to consider sharing supplies locally.
- The licensed powder for injection product should be available during July 2019.

#### Midazolam injection

- The following midazolam presentation continues to have supply issues: Midazolam 1mg/ml solution for injection 5mg/5ml ampoules.
- There has been a delay in the Accord stock of the 5mg/5ml, however, Hameln are now back in stock and can support limited off-contract demand.
  - Accord expect further supplies by the end of w/c 15<sup>th</sup> July.
- Trusts within the Accord regions requiring stock of 5mg/5ml midazolam injection are asked to only order enough from Hameln to cover until Accord stock is expected to be available.
- As a last line option we have confirmed that there is sufficient stock of **Midazolam (5mg/ml) 10mg/2ml** ampoules to support demand for the duration of this supply issue.
- Other strengths are available, but suppliers have confirmed they cannot support this shortage with any other remaining presentations of midazolam injection as there is insufficient stock available to support an increase in demand.
- **We acknowledge this is a high-risk supply issue as per the Rapid Response Report published in 2008 regarding reducing the risk of overdose with midazolam injection in adults and the associated Never Event. The Rapid Response Report and Never Event framework can be found at the following links: [SPS website & Never Event framework](#)**

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### Local action required:

- Review remaining stock holdings of midazolam injection.
- In collaboration with the local Medication Safety Officer and relevant clinical leads, organisations need to undertake local risk assessment to reduce the risk of overdose. Please consider local actions in the following order:
  1. Risk assess supply of remaining stocks of midazolam injection; consider ring fencing supply to highest risk clinical area.
  2. Collaborate and share stock locally where possible.
  3. Where appropriate, please consider alternative drugs for different clinical indications; especially conscious sedation.
  4. **Last line option:** If midazolam (5mg/ml) 10mg in 2ml is the only suitable alternative then a local risk assessment should be undertaken, and risk mitigation actions need to be considered; for example: named patient supply only, raising staff awareness that high strength midazolam is in use (e.g. use of posters / additional labelling). Consider additional checks when preparing and administering, ensure only one strength of midazolam is available in a clinical area (to avoid confusion). Please **do not** switch to any of the other remaining presentations of midazolam injection as there is insufficient stock available to support an increase in demand.
- **As is standard practice, please ensure that flumazenil injection is readily available in all areas where midazolam is used.**
- Please review local protocols and ensure that all those affected are aware of this issue and that particular consideration is given to mitigating the risks associated with switching to alternative higher strength midazolam presentations.

### Mivacron (mivacurium chloride) injection

- Aspen Pharma will be out of stock of 20mg/10ml Mivacron from 6<sup>th</sup> June 2019 to 9<sup>th</sup> August 2019
- Limited supplies of short-dated Mivacron 10mg/5ml ampoules currently remain available through Movianto. Expiry date is October 2019.
- Future deliveries are expected in July (5ml amps) and August (10ml amps).
- There are alternative non-depolarising neuromuscular blocking drugs in the benzyisoquinolinium group available on the market. Please consult local anaesthetists for advice on switching between agents.

### Neurobloc (Botulinum Toxin Type B)

- Neurobloc (Botulinum Toxin Type B) will not be available until late August/early September 2019 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.

### 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.

### Urokinase injection

- Further to our previous communications on urokinase injection, Syner-med have now confirmed that all three urokinase strengths, 10,000unit, 25,000unit and 100,000 unit, are now **out of stock** and anticipated resupply dates are provided below:

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- 10,000IU – further stock available late September;
- 25,000IU – further stock available mid-July;
- 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.
- 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 several strengths of Actiq lozenges with no supplies of the 200mcg or 400mcg strength available now until end of July. 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/>

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

- SOBI, the sole supplier of Ammonaps (sodium phenylbutyrate) 940mg/g granules, has had an interruption in supply due to a change in the marketing authorisation holder.
- Currently, they are unable to advise on a resupply date.
- Ammonaps (sodium phenylbutyrate) 500mg tablets continue to remain available.
- As per UKMI advice, for those patients that are unable to take tablets, Ravicti 1.1g/ml (glycerol phenylbutyrate) liquid is available, **please note** a dose conversion is required.
- Specialist input should be sought prior to switching a patient.
- If switching a patient to Ravicti 1.1g/ml liquid is deemed appropriate; prescribers should consult the dose conversion guidance closely as outlined in the Ravicti SPC and patients should be counselled about the administration of the new formulation.
- Please see the link below for the Ravicti 1.1g/ml (glycerol phenylbutyrate) liquid SPC:  
<https://www.medicines.org.uk/emc/product/2494/smpc>

## COMMERCIAL-SENSITIVE

### Bezalip (bezafibrate) 200mg tablets

- Teva, sole suppliers, are currently out of stock of bezafibrate 200mg tablets until early August 2019.
- A clinical memo from UKMI with advice on alternative options is available here: <https://www.sps.nhs.uk/articles/shortage-of-bezafibrate-200mg-tablets/>
- We have been in contact with the supplier of the suggested alternatives and can confirm that they have sufficient supplies available to support for the duration of this issue.

### Bumetanide 5mg tablets

- Mylan, the sole supplier of bumetanide 5mg tablets, have informed DHSC they are out of stock of this strength with next deliveries planned for the end of July/early August 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 mid/late 2019.
- The affected products are:
  - Carbagen 200mg immediate release tablets – unavailable until mid-2019
  - Carbagen 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/>

### Cardura (doxazosin) XL tablets

- Pfizer have a supply issue with of Cardura XL 4mg and 8mg tablets. Further stock is expected mid-August 2019.
- Pfizer are the sole UK supplier of Cardura XL 8mg tablets but supplies of doxazosin XL 4mg tablets are available from alternative suppliers.

### Epanutin (phenytoin) 30mg/5ml oral suspension

- DHSC are aware of a supply issue with Epanutin oral suspension by Pfizer.
- Please see below for a link to the CAS alert: <https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102868>
- You can sign up to receive Supply Disruption Alerts directly from the Medicine and Healthcare Regulatory Agency's Central Alerting System (CAS) by sending an email to: [safetyalerts@mhra.gov.uk](mailto:safetyalerts@mhra.gov.uk) and requesting this facility.

## COMMERCIAL-SENSITIVE

### 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 of mid-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/>

### Hiprex (methenamine) 1g tablets

- Mylan, sole supplier of this product, are out of stock of methenamine 1g tablets.
- Stock should be available to order by mid-July.
- Specialist importers have identified unlicensed supplies they can bring into the UK from abroad, for urgent orders. Lead times for these products vary between 1-2 weeks.

## Hormone Replacement Therapy products (HRT)

### *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*

- Janssen-Cilag, the supplier of the Evorel transdermal patches has confirmed that supplies of all presentations are currently available.
- However, where supplies for the Evorel 50 and Evorel Conti (24 pack size) are lower than normal, the supplier is applying restrictions on orders as a precaution to ensure stock is maintained.
- Supplies of other HRT patches and products also continue to remain available.

### *Elleste Range*

- Mylan, the sole manufacturer of the Elleste HRT product line has reported that some of the Elleste range (Elleste Solo 1mg, 2mg; Elleste Duet Conti; Elleste Duet 1mg; Elleste Solo MX 40micrograms, 80micrograms patches) are currently unavailable due to manufacturing issues.

## COMMERCIAL-SENSITIVE

- The resupply date for the Elleste range is now expected to be from July 2019.
- As per UKMi advice, please see the table below for equivalent oral alternatives currently available on the market, if required.

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		OOS
Elleste Duet Conti	estradiol 2mg/ norethisterone 1mg	In stock	Kliefem	estradiol 2mg/ norethisterone 1mg	In Stock
Elleste Duet 1mg	estradiol 1mg/ norethisterone 1mg	Out of Stock	NovoFem	estradiol 1mg/ norethisterone 1mg	In Stock

### 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.

## COMMERCIAL-SENSITIVE

### *Ovranette (ethinylestradiol 30 mcg/levonorgestrel 150mcg) tablets*

- Due to capacity constraints, Pfizer will be out of stock of Ovranette tablets from early June until end of August 2019.
- Patients who do not have sufficient supply of Ovranette tablets to last throughout the affected period should be prescribed Rigevidon, Levest, Elevation or Microgynon 30 tablets, if clinically appropriate.
- Prescribers are advised not to switch to Microgynon 30 ED, Leandra or Maexeni during the affected period as they are unable to support.

### Questran Powder for Oral Suspension

- Bristol-Myers Squibb (BMS) are out of stock of Questran Powder 4g sachets and will be receiving no more deliveries before the planned divestment of this product to Cheplapharm on 31<sup>st</sup> July 2019 (see attached letter for further information).
- Supplies of Questran Light sachets are sufficient to support both products, if a switch is deemed clinically appropriate.

### 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/>

### Thorens (coleciferol) 10,000i.u./ml oral drops

- Galen are out of stock of Thorens 10,000i.u./ml oral drops until 8<sup>th</sup> July 2019.
- Several other strength colecalciferol oral drops remain available from alternative suppliers.
- Please see the link below for UKMI advice on alternate preparations:  
<https://www.sps.nhs.uk/articles/shortage-of-thorens-colecalciferol-10-000-i-u-ml-oral-drops/>

### 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.

## Others

### Dalacin (clindamycin) 2% vaginal cream

- Pfizer, sole supplier of clindamycin 2% vaginal cream, are out of stock until end July due to delays in packaging.



## COMMERCIAL-SENSITIVE

- 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>

## Instanyl (fentanyl) nasal spray

- Takeda are currently out of stock of all strengths of Instanyl nasal spray with resupply date as follows: 50mcg mid-July; 100mcg mid-July; 200mcg mid-September.
- 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/>

## 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/>.

### RPH Pharmaceuticals AB

Betnesol Eye Ointment 0.1% w/w x 3g - RPH Pharmaceuticals AB, who distribute this product through Focus Pharmaceuticals, have advised about the discontinuation of Betnesol Eye Ointment 0.1% w/w x 3g and plan to launch a generic Betamethasone Eye Ointment 0.1% w/w x 3g towards the end of 2019.

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.msd-uk.com/products/vaccines.xhtml>.

#### COMMERCIAL-SENSITIVE

- 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.

#### Pneumococcal Polysaccharide Vaccine (PPV23):

- MSD are the sole UK supplier of this vaccine and although under restriction, supplies of the vials and PFS are currently available.
- MSD has introduced a limited quantity of a prefilled syringe (PFS) presentation of PPV23 under the brand name PNEUMOVAX® 23 to supplement the current supply of vials. A combination of growing global demand for pneumococcal polysaccharide vaccines, alongside manufacturing constraints, have led to regular interruptions in supply of PPV to the UK since 2017. The introduction of a PFS presentation of PPV is intended to support the continuity of supply and to help address public health need.
- Pneumovax® 23 in the PFS presentation can be ordered in the same way as the PPV in vials through MSD's distribution partner AAH online at <http://www.aah.co.uk> or by phone on 0344 561 8899.
- For more information about the vaccine, please refer to the Summary of Product Characteristics (SmPC).
- PHE's recommendations and guidance to GPs published in February's edition of PHE's Vaccine Update Bulletin (Page 7), continue to apply.

#### Rabipur (Rabies vaccine)

- GSK is currently experiencing a supply delay with their Rabies vaccine, Rabipur, due to manufacturing constraints.
- Limited supplies are currently available and likely to continue through the first half of 2019.
- Sanofi Pasteur have confirmed they are able to support the full market during this time with their unlicensed Rabies vaccine, Verorab
- NATHNAC have issued further information available at the following link: <https://travelhealthpro.org.uk/news/389/rabies-vaccine-availability>

## Discontinuations

#### Aerivio Spiromax 50 micrograms/500 micrograms inhalation powder

- Teva plans to discontinue Aerivio Spiromax (salmeterol & fluticasone) from the UK market. They indicate they are holding stock to enable patients time to change over to alternatives.
- A number of alternate salmeterol & fluticasone inhalation devices remain available from other suppliers.

#### Aindeem (finasteride) 1mg tablets

- Accord is discontinuing both the generic finasteride 1mg tablets and the brand Aindeem (used for male pattern baldness) with immediate effect.

#### COMMERCIAL-SENSITIVE

- Supplies of finasteride 5mg tablets (used for BPH) remain unaffected and remain fully available.

#### Atarax (hydroxyzine) 10mg and 25mg tablets

- Alliance Pharma are discontinuing 10mg tablets and 25mg and expect stocks to be exhausted in August 2019.
- Generic hydroxyzine 10mg and 25mg tablets remain available from other suppliers.

#### BritLofex (lofexidine) 200mcg tablets

- Britannia, sole supplier, are no longer supplying BritLofex (lofexidine) tablets due to commercial issues (see attached letter).
- We have been in discussion with specialist importer companies and they have been unable to source supplies from abroad.
- UKMI have prepared the following memo, which is available on the SPS website:  
<https://www.sps.nhs.uk/articles/shortage-of-lofexidine-hydrochloride-tablets-200-microgram-britoflex/>

#### Cozaar (losartan) 2.5mg/ml oral solution

- MSD is planning to discontinue Cozaar (losartan) oral solution from the global market and expect UK stock to be exhausted at the end of July 2019. The company has issued comms to customers and specialist paediatric groups.
- There are other angiotensin II receptor blockers licensed for the treatment of hypertension in children from 6 years. Valsartan is also available in the UK as an oral solution so there is a second drug of the same class available
- Patients are advised to speak with their health care practitioner to discuss their treatment options.

#### Dimercaprol 50mg/ml injection

- Advanz Pharma, sole supplier of this product, have been unable to supply for several months and have now confirmed that they will be discontinuing this product.
- See the link below for advice by RCEM/NPIS on antidote availability in Emergency Departments:  
<http://scanmail.trustwave.com/?c=8248&d=k6Xu3H1CL5IR-wsS7AOdJI7vHz4ZQXW-N1bfd1XHwA&u=https%3a%2f%2fwww%2esps%2enhs%2euk%2farticles%2fregional-medicines-optimisation-committee-antidotes-and-rums-position-statement%2f>
- NHS Trusts should contact the NPIS for clinical advice if required.

#### Juliperla (gestodene 75mcg and ethinylestradiol 20mcg) tablets

(please also see OCP products section page 16)

- Accord are discontinuing Juliperla tablets from the market with immediate effect.
- A number of branded alternatives remain available from other suppliers.

#### 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.

#### COMMERCIAL-SENSITIVE

- 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.

#### Potassium Iodate 85 mg tablets

- Alliance Pharmaceuticals are out of stock of potassium iodate 85mg tablets and have no plans to recommence manufacturing of this product.
- Hameln have confirmed they can meet additional demand of their product Thysat (potassium iodide 65mg tablets).

#### Quinine bisulphate 300mg tablets

- Teva are planning to discontinue quinine bisulphate 300mg tablets in August 2019.
- Stocks remain available from several other generic suppliers.

#### Tarivid (ofloxacin) 400mg tablets

- Sanofi are planning to discontinue Tarivid 400mg tablets from the market in July 2019.
- Generic ofloxacin remains available from several other suppliers.

#### Tolterodine 1mg and 2mg tablets

- Teva are planning to discontinue tolterodine 1mg tablets with immediate effect and 2mg tablets in August 2019.
- Stocks remain available from several other generic suppliers.

#### Zantac (ranitidine) 150mg and 300mg tablets

- GSK are planning to discontinue Zantac (ranitidine) 150mg and 300mg tablets from the market in August 2019.
- Ranitidine 150mg and 300mg tablets remain available from a number of other suppliers.

#### Zeridame SR (tramadol) tablets

- Accord plans to discontinue Zeridame SR with immediate effect.
- Alternate branded tramadol SR products remain available from a number of other suppliers.

COMMERCIAL-SENSITIVE

## Resolved (date resolved)

Adrenaline 1:1000 1mL ampoules (07/06/2019)  
Arsenic acid (Trisenox) (17/6/19)  
Constella (linaclotide) 290mcg capsules (12/6/19)  
Cycloserine 250mg capsules (11/6/19)  
Fentanyl 50mcg/ml 2ml injection (21/6/19)  
Idarubicin 10mg injection (12/6/19)  
Labetalol tablets (01/07/19)  
Megestrol (Megace) tablets (8/7/19)  
Metopirone 250mg capsules  
Pentamidine 300mg in 5mL injection (7/6/19)  
Questran Light (colestyramine) 4g sachets (18/6/19)  
Sancuso (granisetron) transdermal patches 3.1mg/24hours (10/6/19)  
Sandimmun (ciclosporin) capsules (17/6/19)  
Sinemet (co-careldopa) tablets (17/6/19)  
Tizanidine 4mg tablets (6/19)  
Voriconazole 200mg injection (3/7/19)  
Hypovase 0.5mg and 1mg tablets (04/07/2019)