NHS
Kent and Medway

Medicines Optimisation Shortages Update for GP Update -14th September 2022

***Shortage update taken from SPS Medicines Supply Toolkit on 14th September 2022. Information provided by DHSC and NHSEI Medicines Supply Teams and published on Specialist Pharmacy Services Medicines Supply Tool. Not formally reviewed by NHS Kent and Medway Medicines Optimisation*.**

SHORTAGE: **Diamorphine 10mg powder for solution for injection ampoules**	**Anticipated re-supply date: 23rd September 2022** **Actions**: All healthcare professionals in primary and secondary care including hospices, who prescribe, dispense or administer diamorphine should continue to work with their local Medication Safety Officer (MSO), pharmacy procurement teams or local lead within their organisation to: • implement the permanent actions set out in the Supply Disruption Alert for diamorphine injection issued in March 2020, which advises that morphine sulfate solution for injection 10mg/ml is the most likely first-line alternative. • if diamorphine injection is required, mitigating actions need to be implemented to reduce the potential risk of overdose if using a diamorphine 10mg ampoule. Additionally, those in secondary care should ensure that: • where patients cannot be treated with alternative opioid agents, contact their Regional Pharmacy Procurement Specialist, who in exceptional circumstances, may be able to facilitate the sharing of stock in cases of urgent clinical need. **Alternatives:** Clinicians in both primary and secondary care are reminded of permanent actions they were recommended to take in the Supply Disruption Alert for diamorphine ampoules issued in March 2020. All morphine preparations remain available and can support an increase in demand during this time. **Considerations and background** **Summary** • Diamorphine 5mg ampoules are now back in stock. • Diamorphine 30mg ampoules are now back in stock. • Diamorphine 10mg ampoules are out of stock until mid-September 2022. • Other diamorphine products are also affected: Shortage of Diamorphine 500mg powder for solution for injection ampoules.
SHORTAGE: **EpiPen 300micrograms/0.3ml (1 in 1,000) solution for injection auto-**	**Anticipated re-supply date: 19 September 2022** **Actions:** Where patients have insufficient supplies to last until the re-supply date, prescribers should:

injectors (Viatris UK Healthcare Ltd)	• consider prescribing an alternative adrenaline auto-injector device. • work in close collaboration with their local pharmacies to understand which devices are available. • Prescribers and pharmacists should work together to ensure patients who are switched to an alternative device are trained appropriately and understand how to use the new device. **Alternatives:** • Emerade solution for injection pens (300mcg and 500mcg) • Jext solution for injection pens (150mcg and 300mcg) **Considerations and background** A weekly order limit of 2 EpiPen 300 microgram auto-injectors and 2 EpiPen Junior 150 microgram auto-injectors per community pharmacy per week has been implemented by Viatris until further notice, to ensure equity of supply across all customers. If supplies above this limit are required, pharmacies may contact Alliance or Viatris who will review orders on a case-by-case basis. **Links** • SmPC EpiPen • SmPC Jext • Smpc Emerade • BNF adrenaline
SHORTAGE: **Rabeprazole 10mg gastro-resistant tablets** **Rabeprazole 20mg gastro-resistant tablets**	**Anticipated re-supply date: Rabeprazole 10mg gastro-resistant tablets 28 tablet - 23 September 2022. Rabeprazole 20mg gastro-resistant tablets 28 tablet - 7 October 2022** **Actions:** **Alternatives:** Alternative proton pump inhibitors remain available.
SHORTAGE: **Voriconazole (VFEND) 200mg/5ml oral suspension**	**Anticipated re-supply date: 23 September 2022** **Actions:** Clinicians working in primary care should: • identify patients who will run out before the resupply date and determine the suitability of switching to tablets; and • if above option is not appropriate (see clinical information below), contact the pharmacy at the initiating trust to determine if they can supply, and if this is not possible, seek clinical advice from specialist on alternative treatment options. Secondary care pharmacy procurement teams working with the local Medication Safety Officer and clinical teams should:

- review local stock holding of voriconazole 40mg/ml oral suspension and conserve remaining supplies for children 2 to <12 years of age and for patients with enteral feeding tubes (see clinical information below); and
- work with their Regional Pharmacy Procurement Specialists (RPPS) to share stock locally, to ensure continuity of care for the two patient groups detailed above.

Clinicians working in secondary care should:

- consider prescribing voriconazole tablets, where clinically appropriate in place of voriconazole oral suspension (see clinical information below); and
- if above option is not appropriate, seek specialist advice on alternative treatment options, including advice from Pharmacy on availability of this treatment as a liquid formulation;
- consider prescribing unlicensed imports if the above options are not clinically appropriate (see clinical information below)

Clinicians should ensure appropriate counselling is provided if any changes are made to patients' prescriptions.

Alternatives:

The following alternatives remain available:

- Voriconazole 50mg, 100mg and 200mg tablets

The following specialist importers have confirmed they can source unlicensed voriconazole 40mg/ml oral suspension (please note there may be other companies that can also source supplies):

- Durbin PLC
- Mawdsley's Unlicensed
- Orifarm UK Pharma
- Smartway Pharma
- Alium Medical

Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary.

Considerations and background

Summary

- Voriconazole 40mg/ml powder for oral suspension is out of stock until mid September 2022.
- Trusts with residual stock should reserve supplies for children 2 to <12 years of age or patients who require administration via enteral feeding tubes.

Clinical Information

Resources on administration of medication to patients with enteral feeding tubes or swallowing difficulties suggest that voriconazole tablets can be crushed and mixed with water for administration. However, there may be a risk of tube blockage in patients who require administration via enteral feeding tubes. The SPC for voriconazole states that oral dose recommendations for children are based on studies in which voriconazole was administered as the powder for oral suspension; bioequivalence between the powder for oral

	suspension and tablets has not been investigated in a paediatric population. Considering the assumed limited gastro-enteric transit time in paediatric patients, the absorption of tablets may be different in this group compared to adults. It therefore recommends use of the oral suspension in children from 2 to 12 years of age. Voriconazole is restricted to specialist initiation, therefore, in patients where off-label crushing of tablets or unlicensed imports of oral suspension are not considered appropriate, specialist advice should be sought on an alternative liquid formulation of an appropriate antifungal **Supporting information** Guidance on ordering and prescribing unlicensed imports: Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information: • The supply of unlicensed medicinal products, Medicines and Healthcare products Regulatory Agency (MHRA) • Professional Guidance for the Procurement and Supply of Specials, Royal Pharmaceutical Society (RPS) • Prescribing unlicensed medicines, General Medical Council (GMC) When prescribing a product that is not licensed in the UK due to a supply issue with the licensed alternative prescribers must indicate on the FP10 prescription that an unlicensed product is required. This can be done in one of the following two ways: • Electronic prescriptions – if the required unlicensed product is shown on electronic prescribing systems, GPs should select: ○ Voriconazole 40mg/ml oral suspension (imported) • Paper prescriptions – where the unlicensed product is not shown on electronic prescribing systems, GPs should use a paper prescription and annotate with the following wording: “special order”. Medicine Supply Notification Number: MSN/2021/061U Links • SPCs for voriconazole preparations • Guide to swallowing tablets
SHORTAGE: **Rifampicin 100mg/5ml oral suspension**	**Anticipated re-supply date: October 14th 2022** **Actions:** **Primary Care Teams** Where further supplies are required before the resupply date, primary care should: • continue to order Rifadin oral suspension in line with historic demand; and • be aware that, where demand exceeds historic use, a prescription validation process will be implemented. Anonymised prescriptions should be sent to Sanofi Customer Services to receive further supplies (UK-GFD-DTPsupply@sanofi.com), if requested. **Secondary Care Trusts** Where further supplies are required before the resupply date, Secondary care Trusts should:

- review the ongoing need for Rifadin oral suspension and switch patients to rifampicin capsules where patients can take a solid oral dosage form and the dosage required can be achieved;
- consider limiting prescriptions for Rifadin oral suspension to a maximum of 1 month's supply to ensure supplies at Trusts last as long as possible;
- order unlicensed supplies from Specialist Importers or Specials Manufacturers where insufficient UK licensed Rifadin oral suspension remains at Trusts
- ensure any outsourced partners (OPD and Homecare) are included in local planning; and
- maintain current practice when referring patients into primary care for ongoing supplies.

Alternatives:

Licensed Alternatives

Rifampicin 150mg and 300mg capsules remain available.

Unlicensed Imports

The following Specialist Importers have confirmed they can source unlicensed Rifadin 100mg/5ml oral suspension. Lead times may vary (please note, there may be other companies that can also source this presentation):

- Durbin PLC
- Mawdsley's unlicensed
- Smartway Pharma
- Target
- Waymade PLC

Specials

The following Specials Manufacturers have confirmed they can supply unlicensed rifampicin 100mg/5ml oral suspension (please note, there may be other companies that can also manufacture this presentation):

- Ascot Labs
- Eaststone
- IPS Pharma
- Nova Laboratories Ltd
- PCCA Ltd

Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary.

Considerations and background

Supply Summary

- Sanofi have limited supplies of Rifadin 100mg/5ml oral suspension with resupply expected w/c 10 October 2022.
- Until w/c 10 October 2022, supplies will only remain available to primary care.
- Secondary care Trusts will need to order unlicensed supplies from Specialist Importers or Specials Manufacturers if current stock holding is insufficient to last until the resupply date.

Guidance on ordering and prescribing unlicensed imports

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information:

	• The supply of unlicensed medicinal products, Medicines and Healthcare products Regulatory Agency (MHRA) • Professional Guidance for the Procurement and Supply of Specials, Royal Pharmaceutical Society (RPS) • Prescribing unlicensed medicines, General Medical Council (GMC) When prescribing a product that is not licensed in the UK due to a supply issue with the licensed alternative prescribers must indicate on the FP10 prescription that an unlicensed product is required. This can be done in one of the following two ways: • Electronic prescriptions – if the required unlicensed product is shown on electronic prescribing systems, GPs should select: o Rifampicin 100mg/5ml oral suspension (imported) • Paper prescriptions – where the unlicensed product is not shown on electronic prescribing systems, GPs should use a paper prescription and annotate with the following wording: "special order". **Medicine Supply Notification Number** **MSN/2022/075** **Links** • **SPC Rifampicin preparations**
SHORTAGE: **Aripiprazole 10mg Tablets**	**Anticipated re-supply date**: **September 5th 2022** **Actions:** Clinicians should: • not initiate any new patients on aripiprazole 10mg tablets; and • not prescribe alternative aripiprazole preparations unless the patient does not have sufficient supplies of aripiprazole 10mg tablets. Where patients do not have sufficient stock of aripiprazole 10mg tablets to last until the resupply date, clinicians should: • consider prescribing higher strength aripiprazole tablets to deliver the same dose if appropriate; or • consider prescribing aripiprazole 5mg tablets, working with local pharmacy teams to understand availability, to deliver the same dose if appropriate, until the resupply date; • ensure that the patient is not intolerant to any of the excipients and is counselled on any changes to their dosing regimen; or • consider prescribing unlicensed products only where licensed alternatives are not appropriate. Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see Supporting Information); or • if the above options are not considered appropriate or available, advice should be sought from specialists on management options. **Alternatives:** **Licensed preparations** Alternative strengths and formulations of aripiprazole remain available, but no individual product can support a full uplift in demand. **Unlicensed preparations** The following specialist importers have confirmed they can source unlicensed aripiprazole 10mg tablets (please note there may be other companies that can also source supplies): • Alium Medical

	• Orifarm • Target Healthcare • Mawdsley's Unlicensed **Considerations and background** **Summary** Branded stock of aripiprazole 10mg tablets are currently available. We continue to monitor the supply situation across all strengths of aripiprazole tablets closely; the 5mg, 15mg and 30mg tablets remain available. **Supporting information** **Guidance on ordering and prescribing unlicensed imports** Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information: • The supply of unlicensed medicinal products, Medicines and Healthcare products Regulatory Agency • Professional Guidance for the Procurement and Supply of Specials, Royal Pharmaceutical Society • Prescribing unlicensed medicines, General Medical Council (GMC) When prescribing a product that is not licensed in the UK due to a supply issue with the licensed alternative prescribers must indicate on the FP10 prescription that an unlicensed product is required. This can be done in one of the following two ways: • Electronic prescriptions – if the required unlicensed product is shown on electronic prescribing systems, GPs should select: ○ Aripiprazole 10mg tablets (imported) • Paper prescriptions – where the unlicensed product is not shown on electronic prescribing systems, GPs should use a paper prescription and annotate with the following wording: "special order". **Medicines Supply Notification Number** **MSN/2022/066** **Links** • **SmPC - aripiprazole**
SHORTAGE: **FemSeven Sequi transdermal patches**	**Anticipated re-supply date: December 31st 2022** **Alternatives:** Specialist importers can source unlicensed products. Lead times vary. Use other available HRT products where appropriate**.**
SHORTAGE: **Methylphenidate prolonged-release tablets**	**Anticipated re-supply date: Xaggitin XL 18mg tablets (Ethypharm UK Ltd) 16 September 2022** **Delmosart 18mg modified-release tablets (Accord Healthcare Ltd) 31 December 2022** **Actions for prescribers:** Where patients have insufficient supplies to last until the re-supply date, clinicians should: • consider prescribing Concerta XL, Delmosart or Xenidate XL brands which can support the market during this time, ensuring that the patient is not intolerant to any of the excipients;

- counsel patients to reassure them that Xaggitin XL, as well as the above mentioned brands, have a similar release profile to Concerta XL (see clinical information); and
- reassure patients that any changes to their prescription will be short-term and for the duration of the supply issue only, and they have the option to switch back to Xaggitin XL once the supply issue is resolved or continue the brand they have been switched to.

Where a patient is due to start methylphenidate treatment, clinicians should:

- defer starting any new patients on methylphenidate (Xaggitin XL) prolonged-release tablets until the supply issue is resolved; and
- consider prescribing one of the brands named above that can support an uplift in demand.

Alternatives:

The following alternative brands of methylphenidate prolonged-release tablets remain available and can support an uplift in demand:

- Concerta XL,
- Xenidate XL

Considerations and background

Summary

- Delmosart 18mg modified-release tablets are out of stock with resupply expected late December 2022.
- Methylphenidate (Xaggitin XL) 27mg, 36mg and 54mg prolonged-release tablets are back in stock.
- Methylphenidate (Xaggitin XL) 18mg prolonged-release tablets are out of stock until mid-September 2022
- Matoride XL prolonged-release tablets remain available but are unable to support an uplift in demand.

Clinical Information

Methylphenidate is a central nervous stimulant available in the UK in various licensed immediate, modified-release, oral, and solid dosage forms. It is a schedule 2 controlled drug, licensed for the treatment of attention deficit hyperactivity disorder (ADHD) in children aged over 6 years and adolescents and is the usual first line treatment for this condition for both children and adults.

All the modified-release methylphenidate preparations include an immediate-release component as well as an extended-release component. This allows for rapid onset of action while avoiding the need to take further doses during the day to maintain effect.

The biphasic release profiles of these products, however, are not all equivalent and contain different proportions of the immediate-release and modified-release component. The BNF states that different versions of modified-release preparations may not have the same clinical effect. To avoid confusion between these different formulations of methylphenidate, prescribers should specify the brand to be dispensed.

Of the modified-release preparations, Delmosart, Xaggitin XL and Xenidate XL tablets have been approved based on bioequivalence data compared to Concerta XL tablets. Thus, these generic brands have been granted replicate marketing authorisation to Concerta XL on the basis

	that they have satisfied the criteria for equivalent release profile for the reference Concerta XL product. Links to further information Concerta XL prolonged-release tablets SmPC Delmosart prolonged-release tablets SmPC Xaggitin XL prolonged-release tablets SmPC Xenidate XL prolonged-release tablets SmPC NICE guideline for attention deficit hyperactivity disorder Extended-release methylphenidate: A review of the pharmacokinetic profiles of available products
SHORTAGE: **Ketorolac 30mg/ml solution for injection ampoules**	**Anticipated re-supply date: September 15th 2022** **Actions for Prescribers:** • Place orders for Pharmanovia ketorolac 30mg/ml ampoules in line with patient demand. **Alternatives:** See supply summary. **Considerations and background** **Supporting Information** Specialist Pharmacy Service Medicines Information advise ketorolac injection is licensed for the short-term management of moderate to severe acute post-operative pain. Treatment should only be initiated in hospitals. The maximum duration of treatment is two days. It has also been used off label in the palliative care setting for intractable cancer pain, by intermittent injections or as a continuous subcutaneous infusion. **Supply Summary** Baxter are out of stock of ketorolac 30mg/1ml solution for injection ampoules until 1st June 2022. Pharmanovia, the only other licensed supplier, are back in stock as of 18th March 2022 and can meet demand.
SHORTAGE: **Rifampicin 300mg / Isoniazid 150mg Tablets**	**Anticipated re-supply date**: **September 16th 2022** **Actions for Prescribers:** Pharmacy procurement, clinical teams (including prescribers, TB nurses, and clinicians), and any outsourced partners (outpatient clinics and Homecare) should work together to: • review current stock holding of Rifinah® 300mg/150mg tablets; • consider limiting prescriptions for Rifinah® 300mg/150mg tablets to a maximum of 1 month's supply to ensure supplies at Trusts last as long as possible; • order rifampicin 300mg capsules and isoniazid 50mg and 100mg tablets where further supplies are required before the resupply date; or • consider the use of unlicensed imports (see supporting information below); Ensure patients are appropriately counselled about any changes to their medications. **Alternatives:**

Rifinah® 150mg/100mg tablets remain available but are unable to support any increase in demand.
Rifampicin 300mg capsules and isoniazid 50mg and 100mg tablets remain available and can support a partial uplift in demand.

Unlicensed Imports

The following specialist importers have confirmed they can source unlicensed rifampicin and isoniazid 300mg/150mg tablets (please note there may be other companies that can also source supplies):

- Alium
- Clinigen PLC
- Durbin
- Target
- Waymade

Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary.

Considerations and background

Supporting Information

Guidance on ordering and prescribing unlicensed imports

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information:

- The supply of unlicensed medicinal products, Medicines and Healthcare products Regulatory Agency (MHRA)
- Professional Guidance for the Procurement and Supply of Specials, Royal Pharmaceutical Society (RPS)
- Prescribing unlicensed medicines, General Medical Council (GMC)

Medicine Supply Notification Number

MSN/2022/073

Links

- **SPC Rifinah preparations**
- **SPC Rifampicin preparations**
- **SPC Isoniazid preparations**

SHORTAGE:
Promethazine (Phenergan) 25mg /1ml solution for injection ampoules
	Anticipated re-supply date: September 30th 2022
	Actions for prescribers:
	NHS Provider Trust pharmacy procurement teams should:
	• review local stock holding of promethazine 25mg/ml injection, including stock being held at ward locations; and
	• estimate if they hold sufficient stock to meet anticipated demand until the re-supply date.
	Where there are insufficient stocks, the organisation should:
	• request mutual aid, facilitated by their Regional Pharmacy Procurement Specialist; or
	• take immediate action and work with appropriate clinical leads and the local Medication Safety Officer (MSO) to review use of promethazine injection and switch to an alternative agent ensuring:
	  ○ impacted clinical areas are made aware of this shortage and local mitigation; and
	  ○ prescribing systems, aide memoires or guidance documents are reviewed and updated as required.
	See Supporting Information section for further information on therapeutic alternatives.
	
	Alternatives: See considerations and background for guidance on alternatives.
	The following specialist importers have confirmed they can source unlicensed promethazine 25mg/ml solution for injection (please note there may be other companies that can also source supplies):
	• Mawdsley's Unlicensed
	• Target Healthcare
	Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary.
	Considerations and background
	Supporting information
	Although promethazine injection is licensed for use as a symptomatic treatment for allergic conditions, as a sedative in adults and children and as an adjunct to sedation in surgery, it is little used in these conditions as there are better treatments available.
	However, promethazine injection is commonly used off-label in rapid tranquillisation in patients who are not considered suitable for oral treatment. NICE guidance for the management of violence and aggression supports the use of intramuscular promethazine (with haloperidol intramuscular injection). In practice, promethazine is also used without haloperidol particularly if there are concerns of cardiovascular disease.
	Therapeutic alternatives in rapid tranquillisation
	Promethazine is regarded as a second-line treatment in patients who do not respond to intramuscularly administered lorazepam or midazolam injections, or a first-line treatment in patients where benzodiazepines are not felt to be clinically appropriate. Potential alternatives to using promethazine in this setting are to administer:
	• lorazepam plus haloperidol;
	• a short-acting antipsychotic agent such as olanzapine or aripiprazole by intramuscular injection; or

	• diazepam. Treatment may need to be individualised to take account of complicating factors such as cardiovascular disease, any history of benzodiazepine misuse, any concerns about illicit drug use, current medications and allergies/intolerances**.** **Guidance on ordering and prescribing unlicensed imports:** **Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information:** • **The supply of unlicensed medicinal products, Medicines and Healthcare products Regulatory Agency (MHRA)** • **Professional Guidance for the Procurement and Supply of Specials, Royal Pharmaceutical Society (RPS)** • **Prescribing unlicensed medicines, General Medical Council (GMC)**
SHORTAGE: **Promethazine Hydrochloride 25mg Tablets**	**Anticipated re-supply date: October 14th 2022** **Actions for prescribers:** Where patients have insufficient supplies to last until the re-supply date, clinicians should: • review patients to determine if this is still the most suitable therapy; • consider prescribing an alternative sedating antihistamine, taking into consideration the indication, ensuring that the patient is not intolerant to any of the excipients and is counselled on the appropriate dose required (see clinical information); • consider prescribing unlicensed products only where licensed alternatives are not appropriate. Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see clinical information); and • if the options suggested are not considered appropriate, advice should be sought from specialists on management options. For the management of nausea and vomiting in pregnancy, clinicians should: • consider prescribing cyclizine 50mg tablets (see clinical information) For patients in health and justice services, clinicians should: • continue to offer non-pharmacological options for sleep hygiene in line with national guidance; • consider prescribing diphenhydramine 25mg tablets or promethazine (Sominex) 20mg tablets (see clinical information); and • note that prescribing should be limited to short courses for periods of acute distress For sedation/behavioural control in mental health services, clinicians should: • refer patients to the appropriate specialist for an individualised review to determine which alternative sedating agent is required (see clinical information). **Alternatives:** Alternative sedating antihistamines remain available. Where these are not suitable, unlicensed supplies of promethazine hydrochloride 25mg tablets may be sourced, lead times vary.

	Availability of alternative promethazine formulations The following alternative promethazine formulations are available **Promethazine hydrochloride 10mg tablets** Availability: Limited stocks available, but cannot support an uplift in demand **Promethazine hydrochloride (Sominex) 20mg tablets** Availability: In stock and can support an uplift in demand **Promethazine teoclate 25mg tablets** Brands include Careway nausea relief, Avomine and LLOYDSPHARMACY travel sickness and nausea Availability: Limited stocks available, but cannot support an uplift in demand **Promethazine hydrochloride 25mg tablets (parallel imports)** Availability: Limited stocks available, but cannot support an uplift in demand **Promethazine hydrochloride 25mg tablets (unlicensed imports of generic and branded supplies)** Availability: Limited quantities can be sourced but can only support a small uplift in demand **Promethazine hydrochloride (Phenergan) 5mg/5ml elixir** Availability: In stock and can support an uplift in demand **Promethazine hydrochloride (Phenergan) 25mg/ml solution for injection** Availability: In stock and can support an uplift in demand **Available alternative sedating antihistamines** The alternative sedating antihistamines listed can only support a full uplift if demand is spread across all agents, with the exception of chlorphenamine 4mg tablets and 2mg/5ml oral solution which can support a full uplift in demand. **Alimemazine** Available presentations include 10mg tablets,10mg/5ml oral solution, 7.5mg/5ml oral solution and 30mg/5ml oral solution Licensed indications • management of urticaria and pruritus • in children aged 2-7 years: pre-medication sedation before general anaesthesia **Cinnarizine** Available presentations include 15mg tablets Licensed indications • Disorders of balance – maintenance therapy for symptoms of labyrinthine disorders, including vertigo, tinnitus, nystagmus, nausea and vomiting such as is seen in Meniere's Disease • Control of motion sickness **Cinnarizine with dimenhydrinate** Available as Arlevert tablets Licensed indication • treatment of vertigo symptoms of various origin in adults **Chlorphenamine** Available presentations include 4mg tablets and 2mg/5ml oral solution

	Licensed indications • Symptomatic control of all allergic conditions responsive to antihistamines, including hay fever, vasomotor rhinitis, urticaria, angioneurotic oedema, food allergy, drug and serum reactions, insect bites. • Symptomatic relief of itch associated with chickenpox. **Cyproheptadine hydrochloride** Available as Periactin 4mg tablets Licensed indications • Acute and chronic allergic and pruritic conditions • Adjunctive therapy to adrenaline and other standard measures for the relief of anaphylactic reactions after the acute manifestations have been controlled **Cyclizine** Available as 5mg tablets Licensed indication • prevention and treatment of nausea and vomiting in adults and children aged 6 years and over **Diphenhydramine** Available as 25mg tablets and 50mg Licensed indications • an aid to the relief of temporary sleep disturbance • Histergan brand also licensed for treatment of allergic conditions **Hydroxyzine** Available as 10mg tablets and 25mg tablets Licensed indications • symptomatic treatment of anxiety in adults. • symptomatic treatment of pruritus associated with urticaria in adults, adolescents and children (≥5-11 years). **Ketotifen** Available as Zaditen 1mg tablets and Zaditen 1mg/5ml elixir Licensed indication • symptomatic treatment of allergic conditions including rhinitis and conjunctivitis. **Considerations and background** **Summary** Limited stock of generic promethazine 25mg tablets remain available. There are limited supplies of other promethazine formulations (see alternatives) **Clinical Information** Promethazine 25mg tablets are licensed for use as an antiemetic and the symptomatic treatment for allergic conditions of the upper respiratory tract and skin including allergic rhinitis, urticaria and anaphylactic reactions to drugs and foreign proteins. They are also licensed for the short-term treatment of insomnia in adults and as a sedative in paediatrics. In Health and Justice services, promethazine 25mg tablets are recommended first line as an alternative to hypnotics such as benzodiazepines and zopiclone or zolpidem. Switching to diphenhydramine or promethazine (Sominex) 20mg tablets will support an easier switch back to promethazine 25mg tablets when

	supplies become available and reflects the national guidance for Health and Justice practice.
	Promethazine (oral) is used in both children and adult mental health services for the management of disturbed behaviour. In many cases it is likely to be considered a first line option in cases where either a benzodiazepine or an antipsychotic (used as a tranquiliser/sedative) is inappropriate. NICE guidance for the management of violence and aggression lists intramuscular promethazine and haloperidol an option. In some trusts oral promethazine is used as an option before embarking on parenteral use.
	NICE CKS guidance notes that although not licensed for the management of nausea and vomiting in pregnancy, promethazine and cyclizine have been used in established practice for many years, with extensive clinical experience of their use in this population.
	Guidance on ordering and prescribing unlicensed imports
	The following specialist importers have confirmed they can source unlicensed promethazine 25mg tablets (please note there may be other companies that can also source supplies):
	• Alium Medical
	• Mawdsley's Unlicensed
	• Target Healthcare
	Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures.
	Please see the links below for further information:
	• Prescribing unlicensed medicines, General Medical Council (GMC)
	• The supply of unlicensed medicinal products, Medicines and Healthcare products Regulatory Agency (MHRA)
	• Professional guidance for the Procurement and Supply of Specials, Royal Pharmaceutical Society
	When prescribing a product that is not licensed in the UK due to a supply issue with the licensed alternative prescribers must indicate on the FP10 prescription that an unlicensed product is required. This can be done in one of the following two ways:
	• Electronic prescriptions – if the required unlicensed product is shown on electronic prescribing systems, GPs should select:
	  ○ Promethazine hydrochloride 25mg tablets (imported); or
	  ○ Pharmacy Action Allerelief (imported)
	  ○ Paper prescriptions – where the unlicensed product is not shown on electronic prescribing systems, GPs should use a paper prescription and annotate with the following wording: "special order".
	Links to further information
	BNF antihistamines
	Nausea/vomiting in pregnancy | CKS | NICE
	RCGP SEG Safer Prescribing in Prisons 2019
	Violence and aggression: short-term management in mental health, health and community settings | Guidance | NICE
	Please refer to the SmPC's for information on alternative preparations

SHORTAGE:	**Anticipated re-supply date: September 9th 2022**

Prilocaine (Citanest 1%) 500mg/50ml solution for injection vials	**Actions for Prescribers:** NHS provider trust pharmacy procurement teams should work with appropriate clinical leads and their local Medication Safety Officer (MSO) to: • identify where prilocaine (Citanest® 1%) 500mg/50ml injection is used within your organisation; • following local risk-assessment switch to an alternative treatment option most appropriate to meet patient requirements (see supporting information); • agree a plan for communicating this supply issue to relevant teams within the organisation; and • consult an anaesthetist for advice where required **Alternatives:** Other injectable local anaesthetics including lidocaine are available; see BNF link in the supporting information **Considerations and background** **Supporting Information** Prilocaine is an amide local anaesthetic of low toxicity, similar to lidocaine. Citanest® 1% is licensed in adults and children aged above 6 months for use in infiltration anaesthesia and nerve blocks. Another prilocaine injection, Prilotekal, remains available, but this is a hyperbaric solution (containing glucose), of higher concentration, and only licensed for use as spinal anaesthesia in short term surgical procedures in adults. Please refer to the links below for further information: BNF treatment summary: local anaesthesia Citanest® 1% Solution for Injection – SmPC Prilotekal® 20mg/ml solution for injection – SmPC
SHORTAGE: **Oxybutynin 3.9mg/24 hours transdermal patches**	**Anticipated re-supply date: September 9th 2022** **Actions for Prescribers:** Clinicians prescribing treatment in primary and secondary care should: • defer initiating new patients on oxybutynin (Kentera®) 3.9mg/24hours transdermal patches until the supply issue resolves; • review patients currently on treatment to determine if this is still the most suitable therapy and where appropriate, consider switching to oxybutynin tablets or oral solution in those not previously on these treatments; or assess risk of a re-trial of these formulations in patients previously treated with them, titrating dose as needed, based on symptoms and tolerability (see clinical advice); or • consider use of another anticholinergic agent, which may be better tolerated; • assess suitability of patients who are unable to tolerate the side-effects of oral oxybutynin or other anticholinergic preparations for mirabegron prolonged-release tablets (see supporting information); and • if above options not suitable, obtain specialist advice. **Alternatives:** **Alternative treatment options** Alternative medicines listed below are licensed for urinary disorders and remain available and can support an uplift in demand.

	Note that oxybutynin (Lyrinel XL®) 5mg and 10mg modified-release tablets are available but cannot support an increase in demand during this time. **Anticholinergic agents** Oxybutynin 2.5mg and 5mg standard release tablets Dose: 5mg BD to TDS (2.5mg BD elderly) Oxybutynin 2.5mg/5ml and 5mg/5ml oral solution Dose: 5mg BD to TDS (2.5mg BD elderly) Solifenacin 5mg and 10mg standard release tablets Dose: 5mg to 10mg OD Solifenacin 1mg/1ml oral suspension Dose: 5mg to 10mg OD Tolterodine 1mg and 2mg standard release tablets Dose: 1mg to 2mg BD Tolterodine 2mg modified release and 4mg modified release capsules Dose: 2mg to 4mg OD **Non-anticholinergic agents** Mirabegron (Betmiga®) 25mg and 50mg prolonged release tablets Dose: 25mg to 50mg OD **Considerations and background** **Clinical advice** Dry mouth is the most common and troublesome adverse effect of anticholinergic medicines and is the main reason for discontinuing oxybutynin. As many of the adverse effects of anticholinergic medicines are dose-related, it is recommended to start at a low dose and titrate according to efficacy and side-effects; older people require lower doses. For patients experiencing side-effects or with inadequate response at maximum dose, changing to a different anticholinergic may be beneficial as side-effect profiles differ. Solifenacin and tolterodine are considered to cause dry mouth to a lesser extent than oxybutynin. Extended-release preparations are also expected to reduce the risk of dry mouth. Oxybutynin (Kentera®) transdermal patches are licensed for the symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in adult patients with unstable bladder. They are prescribed to patients who experience intolerable anticholinergic side-effects from oral oxybutynin. Mirabegron (Betmiga®) is a non-anticholinergic agent, which is NICE approved for treating the symptoms of overactive bladder, only for people in whom anticholinergic drugs are contraindicated or clinically ineffective or have unacceptable side-effects. Appropriateness of this treatment will need to take into account co-morbidities such as hypertension, liver, and renal impairment, as well as interacting medicines. As mirabegron is a prolonged-release tablet, it cannot be crushed. Please refer to the SmPC's for further information: • Oxybutynin (Kentera®) 3.9mg/24hours transdermal patches • Oxybutynin tablets and oral solution • Tolterodine preparations • Solifenacin preparations • Mirabegron (Betmiga®) 25mg and 50mg prolonged-release tablets

SHORTAGE: Levemir Penfill 100units/ml solution for injection 3ml cartridges (Novo Nordisk Ltd)	**Anticipated re-supply date: September 19th 2022** **Actions:** Where patients have insufficient supplies to last until the re-supply date, clinicians should: • prescribe Levemir FlexPen 100 units/ml solution for injection in pre-filled pen • counsel patients on the new formulation and how to use the device as well as monitoring their condition given the change in device **Alternatives:** Levemir FlexPen 100 units/ml solution for injection in pre-filled pen remain available during this time and is able to support a full uplift in demand. **Considerations and background** **Summary** Levemir Penfill 100units/ml solution for injection 3ml cartridges are in limited supply from early-September 2022 until late-September 2022. The issue is expected to be localised with only some regions seeing a stock out. **Links** • Levemir FlexPen 100 units/ml SmPC • Levemir Penfill 100 units/ml cartridges SmPC
SHORTAGE: Methylprednisolone (Medrone) 4mg Tablets	**Anticipated re-supply date: 20th January 2023** **Actions:** Where patients have insufficient supplies to last until the re-supply date, clinicians should: • review patients to determine if this is still the most suitable therapy; • in consultation with the patient, consider switching to prednisolone tablets during the out-of-stock period, taking into account the recommended equipotent doses of prednisolone and methylprednisolone are interchangeable (see Supporting information below); and • monitor patients for disease control and tolerability following switch to prednisolone. **Alternatives:** Prednisolone tablets remain available and can support an uplift in demand. **Considerations and background** **Summary** Methylprednisolone (Medrone) 4mg tablets will be out of stock from 15th September 2022 until mid-January 2023. Methylprednisolone (Medrone) 2mg tablets remain available but cannot support an increase in demand. **Supporting information** **Clinical Information** Methylprednisolone is a synthetic glucocorticoid and a methyl derivative of prednisolone. It is approximately 20% more potent than prednisolone, so 4mg of methylprednisolone has an equivalent anti-inflammatory effect to 5mg of

	prednisolone. Both of these treatments can be given either as a single dose or in divided doses. Links to further information can be found below. Medicine Supply Notification Number MSN/2022/072 Links • SmPC methylprednisolone (Medrone) 4mg tablets • SmPC prednisolone 5mg tablets • BNF table of equivalent anti-inflammatory doses of corticosteroids, including prednisolone
SHORTAGE: **Estraderm MX 100 patches**	**Anticipated re-supply date: 16th September 2022** **Alternatives:** Use other available HRT products where appropriate**.** **Considerations and background** **Supply Summary** • Estraderm MX 100 patches are out of stock with resupply expected w/c 12 September 2022**.** **Additional information:** • Estraderm MX® SmPC
SHORTAGE: **Lidocaine 5% ointment**	**Anticipated re-supply date: 28th October 2022** **Alternatives:** LMX4 (lidocaine 4% w/w) cream remains available. Lower strength lidocaine and lidocaine/prilocaine topical products remain available**.** **Considerations and background** Lidocaine 5% ointment is out of stock until w/c 24th October 2022. There are no other topical 5% lidocaine products available.
SHORTAGE: **Venlalic XL 300mg tablets**	**Anticipated re-supply date: 7th October 2022** **Alternatives:** Venlafaxine (Venlalic XL) 150mg modified release tablets remain available and can support the uplift in demand. **Considerations and background** Venlafaxine (Venlalic XL) 300mg modified release tablets are currently out of stock. Links • SmPC Venlalic XL tablets
SHORTAGE: **Bumetanide 1mg/5ml oral solution sugar free**	**Anticipated re-supply date: 16th September 2022** **Actions:** Where healthcare professionals are unable to obtain bumetanide 1mg/5ml SF oral solution via normal routes of ordering, they should consider the use of specials of bumetanide 1mg/1ml SF oral suspension**.**

	Considerations and background **Supporting Information** **Guidance on ordering and prescribing unlicensed medicines** The following specials companies have confirmed they can manufacture bumetanide 1mg/1ml SF oral suspension (please note there may be other companies that can also source supplies): • Easstone Specials • IPS Pharma • Nova Laboratories • Quantum Pharma Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information: • The supply of unlicensed medicinal products; Medicines and Healthcare products Regulatory Agency (MHRA) • Professional Guidance for the Procurement and Supply of Specials; Royal Pharmaceutical Society • Prescribing unlicensed medicines; General Medical Council (GMC), When prescribing a product that is not licensed in the UK due to a supply issue with the licensed alternative, prescribers must indicate on the FP10 prescription that an unlicensed product is required. This can be done in one of the following two ways: • Electronic prescriptions – if the required unlicensed product is shown on electronic prescribing systems, GPs should select: ○ Bumetanide 1mg/5ml SF oral solution (special order) • Paper prescriptions – where the unlicensed product is not shown on electronic prescribing systems, GPs should use a paper prescription and annotate with the following wording: "special order". **Links** • SmPC bumetanide 1mg/5ml SF oral solution
SHORTAGE: **Bowel evacuation preparations (Moviprep Orange oral powder sachets (Forum Health Products Ltd)**	**Anticipated re-supply date: 7th October 2022** **Actions for prescribers:** **NHS Provider Trust pharmacy procurement teams should:** • review local stock holding of all bowel evacuation preparations, including stock being held at ward locations; consider centralising stock where appropriate; and • estimate if they hold sufficient stock to meet anticipated demand until resupply dates. Where there are insufficient stocks, the organisation should: • conservatively order stock of bowel evacuation preparations in line with projected demand until w/c 3rd October 2022 when the supply situation is expected to stabilise; • liaise with their Norgine account manager to understand stock availability and future delivery dates; and • where the above option is not feasible, request mutual aid, facilitated by their Regional Pharmacy Procurement Specialist. Where the above options are not appropriate:

- consider prescribing alternative bowel evacuation preparations, ensuring the patient is not intolerant to any of the excipients and is counselled on the appropriate dose and volume required (see supporting information below); and
- work with appropriate clinical leads to review use of bowel evacuation preparations ensuring:
    - impacted clinical areas are made aware of this shortage and local mitigations;
    - Patient Group Directions (PGDs) are reviewed and updated as required;
    - urgent cases are prioritised which may include:
        - patients on 2-week cancer pathways;
        - Faecal immunochemical Test (FIT) positive patients;
        - surveillance patients known to be at high risk of cancer; and
        - patients in need of urgent treatment/surgery.

Alternatives:
Citrafleet oral powder 15.08g sachets remain available and can support a partial uplift in demand.
Citramag effervescent powder sachets remain available and can support a partial uplift in demand.
Picolax oral powder 16.1g sachets remain available and can support a partial uplift in demand.
Considerations and background
Summary
Supplies of Plenvu oral powder sachets remain available but may be limited at present, with deliveries due weekly until September.
Limited supplies of Klean-Prep oral powder 69g sachets remain available.
Moviprep oral powder sachets are now back in stock as of 19 August 2022, however, Trusts are reminded to order stocks conservatively until further resupply in early-October 2022.
Clinical Information
Moviprep, Plenvu and Klean-Prep oral powder sachets are licensed for bowel cleansing before a procedure requiring a clean bowel.
Other standard bowel preparations are Picolax oral powder 16.1g sachets, Citramag effervescent powder sachets and Citrafleet oral powder 15.08g sachets. Renal function should be assessed prior to treatment with these alternatives. A low residue diet is also recommended prior to the procedure.
Medicines Supply Notification Number
MSN/2022/071
Links

- Moviprep oral powder sachets
- Plenvu oral powder sachets
- Klean-Prep oral powder 69g sachets
- Citrafleet oral powder 15.08g sachets
- Citramag effervescent powder sachets
- Picolax oral powder 16.1g sachets
- Reducing risk of harm from oral bowel cleansing solutions

SHORTAGE: **Estraderm MX 25 patches**	**Anticipated re-supply date: 16th September 2022** **Alternatives:** Use other available HRT products where appropriate. **Considerations and background** **Supply Summary** • Estraderm MX 25 patches are out of stock with resupply expected mid-September 2022. **Additional information:** • Estraderm MX® SmPC
SHORTAGE: **Atorvastatin (Lipitor) 10mg chewable tablets**	**Anticipated re-supply date:5th September 2022** **Actions for prescribers:** For patients with insufficient supplies, community pharmacists may supply atorvastatin 10mg film-coated tablets or atorvastatin 20mg/5ml oral suspension for patients who cannot swallow tablets, counselling patients on the dose required at the point of dispensing in accordance with the SSP for eligible patients. If the patient is deemed ineligible or does not consent to receive an alternative product via the SSP, clinicians can consider prescribing: • atorvastatin 10mg film-coated tablets; • atorvastatin 20mg/5ml oral suspension for patients who cannot swallow tablets, counselling patients on the dose required at the point of dispensing; or • a suitable alternative medicine. **Alternatives** Atorvastatin 10mg film-coated tablets and atorvastatin 20mg/5ml oral suspension remain available and can support a full uplift in demand. **Considerations and background** **Supply summary** • Atorvastatin (Lipitor®) 10mg chewable tablets are out of stock until late July 2022. • A Serious Shortage Protocol (SSP) was issued on 31/05/2022. **Supporting information** Please refer to the BNF and SPCs for further information on alternative preparations: • Atorvastatin (Lipitor) 10mg chewable tablets SmPC • Atorvastatin 20mg/5ml oral suspension SmPC • Atorvastatin 10mg Film Coated Tablets SmPC • Atorvastatin BNF
SHORTAGE: **Diltiazem (Tildiem Retard) 90mg and 120mg modified-release tablets**	**Anticipated re-supply date:17th October 2022** **Actions for prescribers:** Where patients have insufficient supplies to last until the re-supply date, clinicians should:

	• consider prescribing an alternative twice daily modified-release diltiazem preparation (see clinical information); and • for patients prescribed diltiazem for angina, advise them to report worsening of symptoms, side-effects, and the need to use more GTN; • for patients prescribed diltiazem for hypertension, recheck blood pressure within a month after changing brands, if there are concerns about those who may be less stable. **Alternatives:** **See clinical information** **Considerations and background** **Summary** • Diltiazem (Tildiem Retard) 90mg modified-release tablets are out of stock until w/c 17th October 2022. • Diltiazem (Tildiem Retard) 120mg modified-release tablets will be out of stock from beginning of September 2022 to w/c 17th October 2022. • Other brands of twice daily modified release diltiazem (as capsules) remain available and can support a full uplift in demand. **Clinical Information** Other twice daily modified release preparations containing 90 mg and 120 mg diltiazem that are licensed for the treatment of angina and hypertension include Adizem-SR and Angitil SR. The BNF states that 'different versions of modified-release preparations containing more than 60 mg diltiazem hydrochloride may not have the same clinical effect. To avoid confusion between these different formulations of diltiazem, prescribers should specify the brand to be dispensed'**.** **Medicines Supply Notification Number** **MSN 2022 070** **Links** • BNF Diltiazem • SmPC Tildiem® prolonged release tablets • SmPC Angitil SR® capsules • SmPC Adizem SR® capsules
SHORTAGE: **Morphine (Morphgesic SR) 100mg modified-release tablets**	**Anticipated re-supply date: 30th November 2022** **Actions for prescribers:** Where patients have insufficient supplies to last until the re-supply date, clinicians/prescribers should: • consider prescribing MST Continus 100mg modified release tablets or Zomorph 100mg modified release capsules which are able to support the market during this time; and • ensure that the patient is not intolerant to any of the excipients and is counselled on the appropriate dose and volume required (see considerations and background below). **Alternatives:**

	The following alternatives remain available and can support an uplift in demand: • Morphine (MST Continus) 100mg modified release tablets • Morphine (Zomorph) 100mg modified release capsules **Considerations and background** MST Continus 100mg modified release tablet contains lactose. SPC states "Patients with rare hereditary problems of galactose intolerance, the total lactase deficiency or glucose-galactose malabsorption should not take this medicine." Zomorph 100mg modified release capsules consist of sugar spheres (containing sucrose and maize starch). SPC states "Patients with rare hereditary problems of fructose intolerance, glucose- galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine." **Links** • MST Continus tablets SmPC • Zomorph capsules SmPC

All Serious Shortage Protocols (SPP's) can be found:
https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/serious-shortage-protocols-ssps
Shortage update taken from SPS Medicines Supply Toolkit on 14th September 2022. Information provided by DHSC and NHSEI Medicines Supply Teams and published on Specialist Pharmacy Services Medicines Supply Tool. Not formally reviewed by NHS Kent and Medway Medicines Optimisation. Practices are encouraged to register for access to the SPS website https://www.sps.nhs.uk/ and access this tool directly in real time.