

South East London Guidance on alternatives to prescribing unlicensed Specials in Primary Care

Specials, like all unlicensed medicines, should only be prescribed when there is no available licensed medicine which fully meets the patient's special clinical needs. **This document aims to support clinicians in reviewing their prescribing of unlicensed specials and signpost to relevant local and national guidance for advice.** The medicines listed below (whilst not exhaustive) are those seen most commonly being prescribed across SEL, where licensed, more appropriate and/or cost effective medicines are on formulary and may be a suitable alternative for the patient. If the recommendation/alternative results in a change in liquid concentration, or solid dosage form strength, the patient/carer **MUST** be counselled to ensure they understand any resulting change(s) to administration.

DRUGS PRESCRIBED TO ADULTS	RECOMMENDATION/ALTERNATIVE
Colecalciferol (multiple formulations)	SEL preferred brands: Thorens® 10,000units/ml (200units/drop) oral drops sugar free, Thorens® 25,000unit capsules, Plenachol® 40,000unit capsules, Stexerol D3® 1000 unit tablets, Invita D3® 400 unit capsules Refer to the SEL Adult Vitamin D Guideline Please review if able to purchase OTC in line with self-care guidance. Consult with local borough guidance, and refer to the SEL IMOC self-care — FAQs for Prescribers September 2022.
Co-proxamol 32.5mg/325mg tablets	Based on advice from NHSE (GREY RATING) - Not recommended for prescribing in SEL. Refer to the SEL Prescribing Factsheet and review please.
Cyanocobalamin 1mg MR tablets	Consider switch to licensed 1mg tablet formulation – prescribe as the Orobalin® brand Approved for the treatment of vitamin B12 deficiency only. Refer to the <u>SEL Joint Medicines Formulary</u> for detail.
Gabapentin oral liquids (multiple concentrations)	If liquid formulation is clinically necessary, consider switch to licensed 50mg/ml oral solution sugar free. Consider switch to capsule formulation. Capsules may be opened and the contents dispersed in water/squash/juice for those unable to swallow whole capsules.
Lansoprazole oral liquids (multiple concentrations)	Consider switch to first line choice: 1. Either Omeprazole capsules 2. OR Lansoprazole capsules (if also taking clopidogrel)
	In patients with swallowing difficulties: Omeprazole dispersible tablets or Lansoprazole dispersible tablets (if also taking clopidogrel) In patients with enteral feeding tubes: Lansoprazole dispersible tablets Please review as per SEL Joint Medicines Formulary
Magnesium oral preparations (multiple concentrations and formulations e.g. glycerophosphate, oxide)	First line choice: Magnesium aspartate (magnesium 10mmol) oral powder sachets Second line choice: Magnesium glycerophosphate (magnesium 97.2mg (4mmol) tablets Approved to prescribe for the treatment of hypomagnesaemia only, please refer to the SEL Joint Medicines Formulary
Melatonin oral liquids (various concentrations)	Refer to the SEL Joint Medicines Formulary and consider prescribing of the licensed 2mg MR tablet OR the licensed liquid. Please note the liquid is restricted to use in those with swallowing difficulties, or in patients on a specific dose that is not practical to be given from the 2mg MR tablets.
Riboflavin 100mg MR tablets and 50mg capsules	Approved to prescribe for riboflavin deficiency in metabolic disorders only as per SEL Joint Medicines Formulary. For other indications, please review if patient is able to purchase OTC in line with self-care guidance If a prescription is required please consider prescribing and/or requesting supply of Lamberts brand 50mg capsules as recommended by the British Inherited Diseases Metabolic Group Guidance.
Sertraline oral liquid (multiple concentrations)	If liquid is prescribed due to swallowing difficulties, consider whether the licensed 100mg/5ml concentrate for oral solution, or a crushed and dispersed tablet may be an appropriate alternative in line with guidance from SPS: SSRI suggestions for adults with swallowing difficulties – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice. Note: The licensed liquid contains ethanol and requires dilution prior to administration of each dose – refer to manufacturer's Summary of Product Characteristics for further information.
Sodium chloride 5% eye ointment	Consider prescribing (if clinically suitable) as sodium chloride 5% (Alissa Healthcare) eye ointment 5g preservative free tube as per <u>SEL Joint Medicines Formulary</u> (approved for the treatment of corneal oedema)



DRUGS PRESCRIBED TO	RECOMMENDATION/ALTERNATIVE
CHILDREN	
Colecalciferol (multiple formulations)	SEL preferred brands: Thorens® 10,000units/ml (200units/drop) oral drops sugar free, Plenachol® 20,000unit capsules, Invita D3® 400unit capsules Refer to the SEL Paediatric Vitamin D Guideline for additional dosing and formulation advice. Care is needed when switching to a different liquid concentration. Ensure patient/carer
	understands the change and the new volume for administration.
Dihydrocodeine 10mg/5ml oral suspension	Non-formulary formulation - refer to the SEL Paediatric Formulary for additional dosing and formulation advice
	Consider switch to licensed tablets (off-label) which can be crushed and dispersed in water if required.
Gabapentin oral liquid (multiple	Consider switch to licensed gabapentin 50mg/ml oral solution sugar free
concentrations)	Refer to the SEL Paediatric Formulary for additional dosing and formulation advice.
Glycopyrronium bromide oral liquid	Consider switch to licensed glycopyrronium bromide 400micrograms/ml oral solution sugar free (Sialanar® 320micrograms/ml oral solution)
(multiple concentrations)	Refer to the SEL Paediatric Formulary for additional dosing and formulation advice.
Lamotrigine 50mg/5ml oral liquid	Non-formulary formulation - refer to the SEL Paediatric Formulary for additional dosing and formulation advice
	Consider switch to licensed lamotrigine dispersible tablets available in 2mg, 5mg, 50mg and 100mg strengths.
	If this formulation has been recommended by a hospital specialist team please email the specials team with the relevant details e.g. clinic letter, discharge letter to help support a review.
	Switching formulation may require specialist involvement.
Magnesium oral preparations (multiple	First line choice (children 2 years and above): Magnesium aspartate (magnesium 10mmol) oral powder sachets
concentrations and formulations e.g.	Magnesium glycerophosphate (magnesium 121.25mg/5ml (5mmol/5ml)) oral solution (MagnaPhos®) is reserved for patients under 2 years of age or those who cannot tolerate
glycerophosphate)	magnesium aspartate powder for oral solution.
	Approved to prescribe for the treatment of hypomagnesaemia only. Refer to the SEL Paediatric Formulary for additional dosing and formulation advice. Please note that the magnesium
	content differs between formulations.
Melatonin liquids (multiple concentrations)	The preferred unlicensed oral solution is Kidmel® 1mg/1ml due to a more acceptable excipient profile.
	Refer to the SEL Paediatric Melatonin Guideline for advice on the most appropriate formulation to prescribe, dependent on indication and presence of enteral tube. Melatonin oral solution
	is reserved for use in patients with fine-bore enteral feeding tubes where there is a risk of tube occlusion or if there are compliance issues with the crushed tablets.
Midazolam oromucosal (multiple	Please prescribe by brand. Buccal and oromucosal route terminologies are interchangeable, however presentation on clinical systems may be different. The formulation choice for an
concentrations) or oral liquid	individual patient is dependent on the indication for its use . The formulations have different release characteristics therefore it is vital that the most appropriate one is prescribed and supplied.
	Midazolam is available in several licensed and unlicensed formulations and strengths including:
	Oromucosal (buccal) solution in pre-filled oral syringes – SEL preferred brand is Buccolam®
	Buccal (oromucosal) solutions
	Oral solutions
	Oral solutions
	Refer to the SEL Paediatric Formulary for additional dosing and formulation advice
Omeprazole liquids (multiple	Omeprazole dispersible tablets first-line for patients without enteral feeding tube and dose ≥5mg.
concentrations)	If liquid formulation is clinically appropriate, switch to licensed 20mg/5ml oral suspension sugar free.
	Refer to the SEL Paediatric PPI Pathway and Paediatric Formulary for additional dosing and formulation advice.
Phenobarbital liquids (multiple	Phenobarbital 50mg/5ml alcohol-free oral solution or suspension (unlicensed special) is the recommended formulation and concentration.
concentrations)	Refer to the SEL Paediatric Formulary for additional dosing and formulation advice.



DERMATOLOGY SPECIALIST MEDICINES PRESCRIBED TO CHILDREN AND ADULTS	RECOMMENDATION/ALTERNATIVE
Coal tar and salicylic acid ointment BP	Non-formulary item – refer to the <u>SEL Joint Medicines Formulary</u> and <u>SEL Dermatology Guidelines for Primary Care</u> for suggested alternatives.
Coal tar 5% in clobetasone 0.05% ointment	Non-formulary item – refer to the <u>SEL Joint Medicines Formulary</u> and <u>SEL Dermatology Guidelines for Primary Care</u> for suggested alternatives.
Gentamicin 0.1% cream	Non-formulary item – please review and liaise with relevant trust formulary team
Emulsifying ointment 50%/liquid paraffin 50% ointment	Non-formulary item – refer to the <u>SEL Joint Medicines Formulary</u> and <u>SEL Dermatology Guidelines for Primary Care</u> for suggested alternatives.
Glycopyrronium bromide 0.1% topical solution	RED on SEL Joint Medicines Formulary (hospital prescribing only). Please review if appropriate to continue prescribing.
Glycopyrronium bromide 2% in aqueous cream	Non-formulary item – refer to the <u>SEL Joint Medicines Formulary</u> and <u>SEL Dermatology Guidelines for Primary Care</u> for suggested alternatives.
Glycopyrronium bromide 1% in cetomacrogol cream (Formula A)	Non-formulary item – refer to the <u>SEL Joint Medicines Formulary</u> and <u>SEL Dermatology Guidelines for Primary Care</u> for suggested alternatives.
Lactic acid 10% in aqueous cream	Non-formulary item – refer to the <u>SEL Joint Medicines Formulary</u> and <u>SEL Dermatology Guidelines for Primary Care</u> for suggested alternatives.
Propylene glycol 40% in aqueous cream	Non-formulary item – refer to the <u>SEL Joint Medicines Formulary</u> and <u>SEL Dermatology Guidelines for Primary Care</u> for suggested alternatives.
	RED on SEL Joint Medicines Formulary (hospital prescribing only).
Salicylic acid ointment (in any base) 5%, 10%, 20% and 50%	Please review if appropriate to continue prescribing.

References

- 1) The South East London Joint Medicines Formulary South East London Joint Medicines Formulary Formulary (selondonjointmedicinesformulary.nhs.uk)
- 2) The South East London Paediatric Formulary Clinibee: Configurable Digital Tools for Clinical Care and Research
- 3) South East London Dermatology Guidelines for Primary Care. June 2022. Dermatology-Guidelines-for-Primary-Care-FINAL—October-2022.pdf (selondonics.org)
- 4) South East London Paediatric Guidelines and Pathways SEL IMOC Paediatric guidelines and pathways NHS South East London (selondonics.org)
- 5) South East London Shared Care Agreements SEL IMOC Shared Care Agreements NHS South East London (selondonics.org)
- 6) Medicines for Children <u>Leaflets Medicines for Children</u>
- 7) Specialist Pharmacist Service Guidance, SSRI suggestions for patients with swallowing difficulties, last updated July 2023. SSRI suggestions for adults with swallowing difficulties SPS Specialist Pharmacy Service The first stop for professional medicines advice
- 8) The Royal Pharmaceutical Society. Professional Standards. Prescribing Specials, Guidance for the prescribers of specials. April 2016. professional-standards---prescribing-specials.pdf (rpharms.com)
- 9) The British Inherited Metabolic Diseases Group Formulary (medications). BIMDG: British Inherited Metabolic Disease Group



Appendix I: RAGG Rating Definitions (taken from SEL Joint Medicines Formulary)

Traffic Light Status Information

Status	Description
RED	Specialist or hospital prescribing only. The responsibility for prescribing, monitoring, dose adjustment and review should remain with the specialist or hospital. In very exceptional circumstances a specialist may discuss individual patient need for a RED drug to be prescribed by a GP and the GP should consider informing the Medicines Management team before a decision is made to prescribe for individual patients.
AMB 1	Treatment can be initiated in primary care after a recommendation from an appropriate specialist
AMB 2	Specialist initiation followed by maintenance prescribing in primary care
AMB 3	Specialist initiation with ongoing monitoring required. After dose stabilisation GPs can be requested to take over prescribing responsibilities using the approved IMOC shared care documentation
GREEN	Specialist and non-specialist initiation
GREY	Not recommended for prescribing

Appendix II: Resources to support manipulation of solid oral dosage forms

- 1) Specialist Pharmacy Service: Swallowing Difficulties https://www.sps.nhs.uk/home/guidance/swallowing-difficulties/
- 2) NEWT Guidelines https://www.newtguidelines.com/
- 3) Drug Administration via Enteral Feeding Tubes (available via Medicines Complete) https://www.medicinescomplete.com/
- 4) Medicines for Children How to give medicines: part dose of a tablet or capsule https://www.medicinesforchildren.org.uk/advice-guides/giving-medicines/part-dose-of-a-tablet-or-capsule/
- 5) Guy's and St Thomas' Medicines Information Service can be contacted for additional advice: 020 718 83849 / 83855 / 88750 (Mon to Fri 9am-5.30pm) Email: medicinesinformation@gstt.nhs.uk



Interface Prescribing Support in South East London



Helen Cooper & Sheatha Abumehdi

We provide individualised medicines support to primary care and community pharmacy, with a focus on rationalising prescribing of unlicensed specials across the region.

Contact us: helen.cooper70@nhs.net & sheatha.abumehdi1@nhs.net

Prescribing Support

- Provide recommendations on potential alternatives to unlicensed specials to individual practices in line with SEL formularies, local & national guidance
- Assist with medication reviews for complex paediatric patients
- Advise on prescribing standardised liquid concentrations
- Revise Optimise Rx pop-ups to reflect local guidance

Interface Support

- Assist with prescription queries in primary care and community pharmacy
- Support prescribing from an appropriate care setting
- Liaise with specialist teams across SEL for prescribing and medicines advice
- Support continuity of medicines supply

Formulary and Guidance

- Improve information provision in the SEL formularies
- Gather information on prescribing for non-formulary indications and liaise with relevant specialist teams to implement recommendations
- Create SEL wide guidance including prescribing pathways and shared care agreements

Education and Training

- Individual/practice/PCN level MS Teams calls
- SEL-wide webinars with ICS training hub

Medication Safety and Shortage Support

- · Provide quidance on shortage management via SEL formularies and bulletins
- Consult on medication safety incidents and consider shared learning

Improving medicines value for you and your patients:

- Unlicensed Specials spend reduced by £472,040 (YoY comparison 22/23 and 23/24)
 - 105 specific patient queries responded to (Apr 23-Mar 24)

Please note: this is an interface link advisory service. We do not have access to EMIS and we are unable to offer direct contact with patients/parents/carers.