Community Pharmacy Bulletin

1 April 2021

NHS England and NHS Improvement – South West

Contents

Coming Up

	April	May	June
Week 1	Good Friday 2 April 2021 Easter Sunday 4 April 2021 Easter Monday 5 April 2021	Early May Bank Hoilday Monday 3 May 2021	
Week 2			
Week 3			
Week 4			
Week 5		Spring Bank Holiday Monday 31 May 2021	

Headlines from the Week

NHS England

- None

NHS England South West Regional Team

- Update 116 - NEW Community Pharmacy Advanced service - Lateral Flow Device Distribution Service (sent 30 March 2021)
- Update 117 - Staff Vaccination Survey - South West Pharmacy, Optical and Dental Practices - Deadline Thursday 1st April at 17:00 (sent 30 March 2021)

PSNC Bulletin

- March 2021 Price Concessions - Final Update
- Next publication date for PNAs deferred by 6 months
- Reminder: Prescription charge increases

Changes to South West Region Contact Email Addresses

As of **1 April 2021,** there is now a single point of contact for all email communications to the NHS England and NHS Improvement South West Regional Pharmacy team, please ensure that you use the following email address for all communications going forward england.pharmacysouthwest@nhs.net.

The South West region covers the following areas: -

- Bath & North East Somerset
- Bristol
- Cornwall & Isles of Sicily
- Dorset
- Devon
- Gloucestershire
- North Somerset
- Somerset
- South Gloucestershire
- Swindon
- Wiltshire

Please be aware that the england.bgsw-pharmacy@nhs.net email address will no longer be monitored going forwards.

Covid-19

C-19 Test Distribution Service Added to the Community Pharmacy Contractual Framework

(taken from PSNC Daily Update - 29 March 2021)

A new Advanced service – the NHS community pharmacy COVID-19 lateral flow device distribution service – has been added to the NHS Community Pharmacy Contractual Framework (CPCF) today.

This service, which pharmacy contractors can choose to provide, aims to improve access to asymptomatic COVID-19 testing by making lateral flow device (LFD) test kits readily available at community pharmacies. People will self-administer the tests away from the pharmacy and pharmacy staff will not be involved in the

generation of test results, supporting the reporting of results or the next steps for the person taking the test.

In NHS Test and Trace marketing and communications aimed at the public, the service will be referred to as ***Pharmacy Collect*** and it will allow asymptomatic people to collect LFD test kits, free of charge, from community pharmacies, so they can undertake regular testing as part of the Government's COVID-19 roadmap plan.

Pandemic Delivery Service for CEV Patients Ends 31 March 2021

The Pandemic Delivery Service for clinically extremely vulnerable (CEV) patients finished on 31 March 2021. Community pharmacy contractors are therefore reminded that no further deliveries should be made to these patients, under this service, after this date.

The end of the service follows advice from the Government that from 1 April 2021, CEV patients are no longer required to shield, all CEV patients should have received a letter notifying them of this.

The letter contains guidance for CEV patients on several areas, including visiting pharmacies and advises that they may still want to ask friends, family or volunteers to collect medicines for them or that the NHS Volunteer Responders programme* is still available to help support those who need it. Therefore, if contractors receive requests for delivery of prescriptions from CEV patients, please signpost them to this programme if they do not have anyone who can collect their medicines for them.

Claims for the Pandemic Delivery Service for CEV patients will be accepted by the NHS Business Services Authority (NHSBSA) via the Manage Your Service (MYS) portal; claims must be submitted by 5 April 2021. Later claims will not be processed.

Regulatory Dispensations Update and 31 March Deadlines

(taken from PSNC Daily Update - 29 March 2021)

At the end of last year PSNC agreed a number of regulatory dispensations for contractors with the Department of Health and Social Care (DHSC) and NHS England and NHS Improvement (NHSE&I).

This week there have been two deadline extensions, to the Secretary of State's declaration of an emergency under the regulations and to the dispensation from patient's charge exemption signatures on prescriptions and dispensing tokens:

Secretary of State Declaration of Emergency
The period of emergency declaration has been extended to 30th June 2021 in an amendment to the Directions. This allows contractors to request and NHSE&I to grant temporary flexible opening hours (days or times) by setting out the reasons for the request and giving 24 hours' notice.

Having given 24 hours' notice to NHSE&I with reasons for the request, and in the absence of a response from NHSE&I, contractors may start the flexible provision of opening hours, but must return to normal opening hours if the request is subsequently refused.

Temporary relocations during the emergency are also permitted, see details of the procedure on the PSNC network resilience webpage.

Extension of Temporary Suspension of Signatures on Prescriptions and Token Submission Requirements
As part of the social distancing measures to limit the spread of the coronavirus and to avoid cross contamination by minimizing the handling of any paperwork when patients collect their prescription medicines, Ministers in England agreed to temporarily suspend the need for patient signatures on NHS

prescription forms. The suspension, which came into effect from 1 November 2020 was initially expected to end on the 31 March 2021 and is now extended for a further three months until 30 June 2021.

Whilst the suspension of signature requirements remains in place, contractors are not required to submit EPS tokens (other than those used for SSP claims) to the NHS Business Services Authority (NHSBSA). PSNC has published updated guidance on the changes to the dispensing and end of month submission processes as well as important reminders for pharmacy staff on the correct completion of exempt or paid declarations on the reverse of prescription forms and EPS tokens, it also highlights the key changes to be aware of for dispensing and the end of month submission processes including:

The changes will be kept under review and the suspension date may be brought forward or extended further if there continues to be a cross-infection risk. The temporary suspension will be lifted as soon as it is deemed safe for patients to resume signing forms.

31 March Deadlines
Contractors are also reminded of the dispensations previously agreed with DHSC and NHSE&I that relate to the usual 31 March deadlines.

Topic	Change and Further Information
NHSE&I determined audit	Requirement waived for 2020/21.
NHSE&I and contractor determined clinical audit	Requirement waived for 2020/21.
Community Pharmacy Patient Questionnaire	Requirement waived for 2020/21.
Data Security and Protection Toolkit 2020/21	Deadline for completion extended to 30th June 2021. No action will be taken against contractors that have not completed the 2019/20 Toolkit if they are working to complete the 2020/21 Toolkit.
Complaints return	At the start of the outbreak NHSE&I indicated that annual complaints submissions would not be required during the pandemic and no complaints return is needed at the end of the year 2020/2021.

The full updated briefing can be found at: PSNC Briefing 045/20: Regulatory and contractual dispensations agreed to assist contractors with the ongoing COVID-19 pandemic

---

Medicine Supply Notifications (MSNs) and Serious Shortage Protocol (SSPs)

Medicine Supply Notifications (MSNs)

Please find attached Medicine Supply Notifications for:

- A Tier 2 medicines supply notification chloral hydrate 143.3mg in 5ml oral solution
- A Tier 2 medicines supply notification ranitidine all formulations (update)

The table below provides a summary of the attached MSNs:

Medicine	Out of stock until	Alternatives
Chloral hydrate 143.3mg in 5ml oral solution	September 2021	UK specials have been sourced

Medicine	Out of stock until	Alternatives
Ranitidine all formulations (update)	Until further notice	See MSN attached for further guidance

There have also been changes to the resupply dates of the medicines listed below.

Please note that supply issues that have been categorised as tier 1 or 2, DHSC and the MSRG have requested that the NHSE&I commissioning routes are used to reach community pharmacy and GP Practices. More serious supply issues are communicated via the Central Alerting System for action.

Original MSN reference	Date of original MSN/SDA	Supply issue	Resupply date originally communicated	Updated resupply date as of w/c 29 Mar 2021
MSN/2021/007	08/02/2021	Fluoxetine 40mg capsules	end March 2021	late May 2021
MSN/2020/043-U3	18/03/2021	Norinyl-1 tablets	w/c 22 March 2021	w/c 2 August 2021
MSN/2020/043-U3	18/03/2021	Yiznell tablets	w/c 29 March 2021	w/c 19 April 2021

Please note that supply issues that have been categorised as tier 1 or 2, DHSC and the MSRG have requested that the NHSE&I commissioning routes are used to reach community pharmacy and GP Practices. More serious supply issues are communicated via the Central Alerting System for action.

Serious Shortage Protocol

Due to ongoing supply issues, the Serious Shortage Protocol currently in effect for fluoxetine 10mg tablets (SSP05) and fluoxetine 40mg capsules (SSP009) are being extended. Currently they are due to end tomorrow, Wednesday 31 March.

The end date for both SSPs will now be **Monday 17 May 2021**.

If you have any questions regarding the SSP please contact the NHS Prescription Service:

Email: nhsbsa.prescriptionservices@nhsbsa.nhs.uk
Telephone: 0300 330 1349
Textphone: 18001 0300 330 1349

To access the latest information about SSPs (including supporting guidance), please visit the NHS BSA Website

---

Useful Information

NHS England & Improvement – South West Region Community Pharmacy Contract Management Team contact information

Team Member	Telephone	Address
Jenny Collins	07979 308749	**South West Region Postal Addresses**
Sharon Greaves	07900 715295	
Les Riggs	07730 371074	NHS England and Improvement – South West Peninsula House

Mary Cotton	07920 288191	Kingsmill Road Tamar View Industrial Estate Saltash, PL12 6LE Or NHS England and Improvement – South West Sanger House, 5220 Valiant Court Gloucester Business Park, Brockworth Gloucester, GL3 4FE Or NHS England and Improvement – South West Jenner House, Avon Way Langley Park Chippenham, SN15 1GG *Please note all our offices are currently closed, please do not send post and use email wherever possible* Email: england.pharmacysouthwest@nhs.net
Michele Toy	07568 431890	
Sarah Lillington	07920 834445	
Sharon Hodges	07702 411295	
Tracey Howes	07730 380479	
Chris Yengel	07769 963478	
Kath Hughes	07730 374739	
Hayley Colledge	07900 713005	
Lesley St Leger	07730 381871	
William Anderson	07783 821721	
Stacey Burch	07730 391418	

Webpages

Please see our websites for more information and any blank templates, forms and documents:

Cornwall & Isles of Scilly, Devon, Bristol, Dorset, North Somerset, Somerset and South Gloucestershire

BaNES, Gloucestershire, Swindon or Wiltshire

Interpretation and Translation Services

Department of Health & Social Care

NHS

UPDATE:

Update to communications issued 16/06/2020
Material updates in **bold**.

Medicine Supply Notification

MSN/2020/025-U3

Ranitidine: All formulations

Tier 2 – medium impact*

Date of issue: 30/3/2021

Summary:

- **All preparations of ranitidine (tablets, effervescent tablets, oral solution and injection) are out of stock until further notice.**
- **Following recent advice from the EMA, the MHRA have suspended all licenses for ranitidine products.**
- All formulations of ranitidine are affected due to on-going regulatory investigations into the presence of the contaminant, N-nitrosodiethylamine (NDMA), in samples of ranitidine active substance.
- UKMi have provided clinical advice regarding alternatives to ranitidine preparations **(see Appendix 1)**.

Actions Required

All clinicians in primary and secondary care who prescribe ranitidine preparations should consider the following advice to manage patients;

- Ranitidine 50mg/2ml injection
  - review the previous disruption alert, for advice on switching to alternative agents as appropriate **(see Appendix 1)**
- Oral ranitidine preparations
  - continue to follow guidance on switching, as per UKMi advice mentioned in the previous alert **(see Appendix 1)**

*Classification of Tiers can be found at the following link: **A Guide to Managing Medicines Supply and Shortages**.

Supporting Information

At present, in Europe all suppliers of ranitidine's active ingredient have had their Certificate of Suitability (CEP) suspended. Therefore, until regulatory investigations are complete, no further supplies of ranitidine products can be manufactured. **Further information can be found here**.
.

Ranitidine injection;

- Supplies of alternate IV proton-pump inhibitors (PPI's) remain available (see Table 3 below).

Ranitidine oral products;

- There has been no change to the supply situation or regulatory position on oral ranitidine products since the previous update.
- Supplies of alternate oral PPIs remain available.
- Further information on supply issues affecting some H2 receptor antagonists can be found in MSN/2019/020-U3.
- Prior to prescribing, clinicians should liaise with their pharmacists to understand local stock availability (including resupply dates) of clinical alternatives.

Alternative preparations;

- UKMi have produced a summary of suitable clinical alternatives;
    - Alternative oral acid suppressants for the main indications of oral ranitidine in adults (see Table 1 below)
    - Alternative oral acid suppressants for gastro-oesophageal reflux disease in children (see Table 2 below)
    - Alternative parenteral acid suppressants covering main indications of intravenous ranitidine in adults (Table 3 below)

Enquiries

If you have any queries, please contact DHSCmedicinesupplyteam@dhsc.gov.uk

Department of Health & Social Care

NHS

Appendix 1:

Table 1 Alternative oral acid suppressants for the main indications of oral ranitidine in adults

Before switching to another agent, review if patients still require treatment or could be stepped down to an antacid or alginate.

Acid suppressant	Formulation	GU/DU treatment	GU/DU prophylaxis	GORD	NSAID associated GU/DU treatment/ prophylaxis	Comments
Proton pump inhibitors						
Omeprazole*	Capsules, tablets and dispersible tablets: 10mg,20mg,40mg	20-40mg OD	10-40mg OD (DU) 20-40mg OD (GU)	20-40mg OD (treatment) 10-40mg OD (long term management after healed reflux oesophagitis) 10-20mg OD symptomatic GORD	20mg OD (prevention and treatment)	**not to be prescribed with clopidogrel due to risk of reducing its antiplatelet efficacy* Losec MUPS® not licensed for use via enteral feeding tubes, however there is extensive experience of using via this route in practice.
Lansoprazole	Capsules and dispersible tablets: 15 and 30mg	30mg OD	UL (15-30mg OD) ¥	30mg OD (treatment) 15-30mg (prevention) 15-30mg OD (symptomatic GORD)	30mg OD (treatment) 15-30mg (prevention)	Orodispersible tablets licensed for administration via nasogastric (NG) tubes.
Pantoprazole	Tablets 20 and 40mg	40-80mg OD	UL (20-40mg OD) ¥	20mg OD symptomatic GORD 20-40mg OD long term management and prevention of relapse	20mg OD (prevention)	

*Classification of Tiers can be found at the following link: A Guide to Managing Medicines Supply and Shortages.

Acid suppressant	Formulation	GU/DU treatment	GU/DU prophylaxis	GORD	NSAID associated GU/DU treatment/ prophylaxis	Comments
Proton pump inhibitors (continued)						
Esomeprazole*	Tablets, capsules 20 and 40 Granules 10mg	UL (20-40mg OD) ¥	UL (20-40mg OD) ¥	40mg OD (treatment) 20mg OD (prevention and symptomatic treatment)	20mg OD (prevention and treatment)	**not to be prescribed with clopidogrel due to risk of reducing its antiplatelet efficacy* Granules are licensed for administration via NG or gastric tubes.
Rabeprazole	Tablets 10 and 20mg	20mg OD	UL (10-20mg OD) ¥	20mg OD (treatment) 10-20mg long term maintenance 10mg OD symptomatic GORD	UL	
H2-receptor antagonists						
Nizatidine	Capsules 150mg	150mg BD or 300mg OD	150mg OD	150mg-300mg bd	150mg BD or 300mg OD (treatment)	See above for details of supply issue and mitigation measures
Famotidine	Tablets 20mg and 40mg	40mg OD	DU 20mg OD	20mg BD (but for erosion/ulcer linked to reflux 40mg BD for 6-8 weeks)	UL	See above for details of supply issue and mitigation measures
Cimetidine*	Tablets 200, 400 and 800mg Liquid 200mg/5mL	400mg BD OR 800mg ON (up to 400mg QDS)	400mg ON up to BD	400mg QDS	400mg BD (treatment)- see SPC for other dose regimens	See above for details of supply issue and mitigation measures No data on crushing tablets **caution as CYP P450 inhibitor; care with drug interactions- consult SPC*

Key:, GU: gastric ulcer, DU: duodenal ulcer; PU: peptic ulcer; GORD: gastroesophageal reflux disease, UL: unlicensed

¥ Based on PPI dose equivalence table for severe oesophagitis in NICE guideline (CG184) update (2014): https://www.nice.org.uk/guidance/cg184/chapter/Appendix-A-

Department of Health & Social Care

NHS

Table 2: Alternative oral acid suppressants for gastro-oesophageal reflux disease in <u>children</u> [Refer to BNFC or local paediatric formulary for other indications/off label use]

Before switching to another agent, review if patients still require acid suppression or if could be stepped down to an antacid

Acid suppressant	Formulation	Licensed age group	Dose	Comments
Proton pump inhibitors				
Omeprazole	Capsules, tablets and dispersible tablets: 10mg,20mg,40mg Oral suspension 2mg/ml and 4mg/ml *In the absence of the licensed liquid being available, consider using an unlicensed liquid (manufactured special). However, there is only limited evidence of efficacy.*	> 1 year and ≥ 10 kg	<u><2.5kg</u> 0.7mg-1.4mg/kg to 3mg/kg/day <u>2.5 – 7kg</u> 5mg to 3mg/kg/day (max10mg) <u>7 - 15kg</u> 10mg to 20mg OD <u>>15kg</u> 20mg to 40mg OD	• Losec MUPS® tablets may be dispersed in water (do not crush tablet) for oral liquid administration. Halve 10mg tablet before dispersing for 5mg dose. • Losec MUPS® not licensed for use via enteral feeding tubes, however there is extensive experience of using this route in practice (NB: granules ~ 0.5mm diameter and have tendency to block fine-bore feeding tubes [<8Fr]) • Esomeprazole granules are licensed for administration down tubes ≥6Fr, • *Liquid may be required in age<1 year with nasogastric (NG) or gastric tubes < 8 Fr or in patients intolerant/allergic to excipients in* esomeprazole granules. ** Not to be prescribed with clopidogrel due to risk of reducing its antiplatelet efficacy*
Esomeprazole	Tablets, capsules, 20 and 40mg	≥12 years	20-40mg OD	Granules licensed for administration via enteral tube *≥6 Fr* ** Not to be prescribed with clopidogrel due to risk of reducing its antiplatelet efficacy*
	10 mg gastro-resistant granules for oral suspension	1-11 years	Weight≥10 - <20 kg:10mg OD Weight ≥20 kg: 10-20mg OD	
Pantoprazole	Tablets 20 and 40mg	≥12 years	20 mg OD	
Lansoprazole	Capsules and dispersible tablets: 15 and 30mg	No paediatric licence but used off label in this population	Off label use: <u>Infant 2.5kg – 5kg</u> 3.75mg (1/4 of a 15mg tablet) OD <u>5 – 10kg</u> 7.5mg (1/2 a 15mg tablet) OD	<u>Dispersible tablets</u> • Excipients include aspartame. • Dose should be rounded up or down to nearest solid dosage form i.e. half or quarter of tablet. • Halve or quarter tablet before dispersing in water for oral liquid administration. Stir thoroughly before administration.

*Classification of Tiers can be found at the following link: **A Guide to Managing Medicines Supply and Shortages**.

			10 - 30kg 15mg OD >30kg 30mg OD	• Licensed for administration via NG tube (can be dispersed in 10mL water and flushed down tube > 8Fr). • For fine-bore tubes <8Fr, dissolve contents of capsule in 8.4% sodium bicarbonate before administration). • Lansoprazole dispersible tablets are generally easier to use than omeprazole. When using feeding tubes of gauge under 8Fr in patients over 2.5kg.
Acid suppressant	**Formulation**	**Licensed age group**	**Dose**	**Comments**
Proton pump inhibitors (cont'd)				
Rabeprazole	Tablets 10mg and 20mg	No paediatric licence	Off label use 1-11 years; <15kg: 5mg OD ≥15kg: 10mg OD ≥12 years: 20mg OD	Crushing is not recommended. Not suitable for enteral tube administration
H2-receptor antagonists				
Cimetidine	Tablets 200mg, 400mg and 800mg Liquid 200mg/5mL	>1year	>1 year 25-30mg/kg per day in divided doses Use in age< 1 year not fully evaluated; 20mg/kg/day in divided doses has been used	See above for details of supply issue and mitigation measures No data on crushing tablets. *Caution as CYP P450 inhibitor; care with drug interactions- consult SPC*
Nizatidine	Capsules 150mg	No paediatric licence	Off label use 6 months to 11 years 5-10mg/kg/day in 2 divided doses ≥12 years 150mg BD	See above for details of supply issue and mitigation measures Not suitable to be used via enteral feeding tubes, as whilst drug dissolves in water, excipients do not and may coat and block tube.
Famotidine	Tablets 20mg and 40mg	No paediatric licence	Off label use: 1 to ≤3 months 0.5mg/kg/dose OD ≥3 months to <1 year 0.5mg/kg/dose BD 1 to 16 years 0.5mg/kg/dose BD (maximum 40mg dose)	See above for details of supply issue and mitigation measures Without crushing, tablets will disperse in water, in 2-5 minutes. This process can be quickened by crushing and mixing tablets with water for administration No information available on giving resulting suspension via enteral feeding tubes.

***References**: SPCs, Handbook of Drug Administration via Enteral Feeding Tubes, The NEWT Guidelines for administration of medication to patients with enteral feeding tubes or swallowing difficulties, Evelina London Paediatric Formulary, BNFC, Paediatric & Neonatal Dosage Handbook, 23rd ed*

***Please note:** Any decision to prescribe off-label must take into account the relevant GMC guidance and NHS Trust governance procedures for unlicensed medicines. Prescribers are advised to pay particular attention to the risks associated with using unlicensed medicines or using a licensed medicine off-label.*

Table 3: Alternative parenteral acid suppressants covering main indications of intravenous ranitidine in adults

The need for a parenteral treatment should be assessed and if considered necessary the following injectable proton pump inhibitors may be considered to offer a suitable clinical alternative to intravenous ranitidine

Acid suppressant	Gastric acid suppression in surgical procedures	Prophylaxis of stress ulceration	Conditions where acid suppression needed but oral route not available	Comments
Omeprazole 40 mg Powder for Solution for Infusion	***Not licensed*** Suggest stat dose of 40mg given as an IV infusion over 20-30 minutes.	***Not licensed*** Suggest 40mg once daily given as an IV infusion over 20-30 minutes	Suggest 20-40mg once daily is adequate for most conditions however for conditions such as Zollinger Ellison syndrome, higher doses are needed starting from 60mg daily.	Contra-indicated in patients with previous hypersensitivity reaction to omeprazole or the excipients contained in the injection and in patients taking nelfinavir. For stat dose – potential for drug interactions not likely to be clinically significant. However, when repeat doses are needed the potential for adverse drug interactions should be assessed. This is especially important for patients taking concomitant clopidogrel or the antiretroviral medicines atazanavir or nelfinavir. In patients taking clopidogrel, pantoprazole may be a better choice of PPI. Patients treated with a proton pump inhibitor rather than ranitidine may be more likely to develop electrolyte abnormalities such as hyponatraemia or hypomagnesaemia.
Pantoprazole 40 mg powder for solution for injection	***Not licensed*** Suggest stat dose of 40mg given as an IV bolus over at least 2 minutes or infused over at least 15 minutes	***Not licensed*** Suggest 40mg once daily given as an IV bolus over at least 2 minutes or infused over at least 15 minutes	Suggest 40mg once daily is adequate for most conditions however for conditions such as Zollinger Ellison syndrome higher doses are needed starting from 80mg daily	Contra-indicated in patients with previous hypersensitivity reaction to pantoprazole or the excipients contained in the injection. For stat dose – potential for drug interactions not likely to be clinically significant. However when repeat doses are needed the potential for adverse drug interactions should be assessed. This is especially important for patients taking the antiretroviral medicines atazanavir or rilpivirine. In patients taking clopidogrel, pantoprazole may be a better choice of PPI. Patients treated with a proton pump inhibitor rather than ranitidine may be more likely to develop electrolyte abnormalities such as hyponatraemia or hypomagnesaemia.

Esomeprazole 40 mg powder for solution for injection/infusion	***Not licensed*** Suggest stat dose of 40mg given as an IV bolus over at least 3 minutes or infused over 10-30 minutes	***Not licensed*** Suggest 40mg once daily given as an IV bolus over at least 3 minutes or infused over 10-30 minutes	Suggest 40mg once daily is adequate for most conditions however for conditions such as Zollinger Ellison syndrome (unlicensed use of injection), higher doses needed.	Contra-indicated in patients with previous hypersensitivity reaction to esomeprazole or the excipients contained in the injection and in patients taking nelfinavir. For stat dose – potential for drug interactions not likely to be clinically significant. However, when repeat doses are needed the potential for adverse drug interactions should be assessed. This is especially important for patients taking concomitant clopidogrel or the antiretroviral medicines atazanavir or nelfinavir. In patients taking clopidogrel, pantoprazole may be a better choice of PPI. Patients treated with a proton pump inhibitor rather than ranitidine may be more likely to develop electrolyte abnormalities such as hyponatraemia or hypomagnesaemia.

Based on PPI dose equivalence table for severe oesophagitis in NICE guideline (CG184) update (2014): https://www.nice.org.uk/guidance/cg184/chapter/Appendix-A- , British National Formulary Issue no 78 (Sept 2019- Mar 2020) and the most recent versions of the Summary of Product Characteristics for ranitidine injection, omeprazole injection, pantoprazole injection and esomeprazole injection (all accessed via eMC website: www.medicines.org.uk)

Department of Health & Social Care

NHS

Medicine Supply Notification

MSN/2021/019

Chloral Hydrate 143.3mg in 5ml oral solution

Tier 2 - medium impact*
Date of issue: 30/03/2021

Summary

- Chloral hydrate 143.3mg in 5ml oral solution is out of stock until September 2021.
- Specials manufacturers have confirmed they can manufacture chloral hydrate 143.3mg in 5ml oral solution to meet demand of the licensed product.

Actions Required

Where patients have insufficient supplies, clinicians should:

- review ongoing need for treatment;
- prescribe 143.3mg in 5ml chloral hydrate solution as a special if ongoing treatment is deemed necessary (see Supporting Information below).

Supporting Information

Guidance on ordering and prescribing specials and imports

The following specials manufacturers have confirmed they can manufacture chloral hydrate oral solution (please note, there may be other companies that can also manufacture this product):

- Ascot labs - 143.3mg in 5ml oral solution
- Alium Medical - 143.3mg in 5ml oral solution*
- Target Healthcare - 143.3mg in 5ml oral solution*

**Please note these products are not batch manufactured and the supplier will only provide a certificate of conformity (CoC). Suppliers providing batch manufactured products will provide a certificate of analysis (CofA).*

*Classification of Tiers can be found at the following link: https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/

Department of Health & Social Care

NHS

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)

Chloral hydrate 143.3mg in 5ml oral solution – special

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, GP's should select:
  - chloral hydrate 143.3mg in 5ml oral solution (special order)

- Paper prescriptions - where the unlicensed product is not shown on electronic prescribing systems, GP's should use a paper prescription and annotate with the following wording: "special order".

Enquiries

If you have any queries, please contact DHSCmedicinesupplyteam@dhsc.gov.uk

*Classification of Tiers can be found at the following link: https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/