



29 July 2022

## **Medicine Supply Alert Notice**

### **Promethazine hydrochloride 25mg tablets**

**Priority: Level 2\***

**Valid until: until Mid-August 2022**

#### **Issue**

1. Promethazine hydrochloride 25mg tablets are out of stock until mid-August 2022.
2. There are limited supplies of other promethazine formulations (see Table 1).
3. Alternative sedating antihistamines remain available. Where these are not suitable, unlicensed supplies of promethazine hydrochloride 25mg tablets may be sourced, lead times vary.

#### **Advice and Actions**

4. 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 additional 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 additional information); and
  - if the options suggested in this MSAN are not considered appropriate, advice should be sought from specialists on management options.
5. For the management of nausea and vomiting in pregnancy, clinicians should:
  - consider prescribing cyclizine 50mg tablets (see additional information)
6. 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<sup>®</sup>) 20mg tablets (see additional information); and
  - note that prescribing should be limited to short courses for periods of acute distress.
7. 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 additional information).

## Additional Information

### Clinical Information

Table 1: Availability of alternative promethazine formulations

Alternative promethazine preparations	Availability	Capacity to uplift
Promethazine hydrochloride 10mg tablets	Limited stocks available	Cannot support an uplift in demand
Promethazine hydrochloride (Sominex <sup>®</sup> ) 20mg tablets	In stock	Can support a small uplift in demand
Promethazine teoclate 25mg tablets (brands include Careway nausea relief <sup>®</sup> , Avomine <sup>®</sup> , LLOYDSPHARMACY travel sickness and nausea <sup>®</sup> )	Limited stocks available	Cannot support an uplift in demand
Promethazine hydrochloride 25mg tablets (Parallel imports)	Limited stocks available	Cannot support an uplift in demand
Promethazine hydrochloride 25mg tablets (unlicensed imports of generic and branded supplies)	Limited quantities can be sourced	Can support a small uplift in demand
Promethazine hydrochloride (Phenergan <sup>®</sup> ) 5mg/5ml elixir	In stock	Cannot support an uplift in demand
Promethazine hydrochloride (Phenergan <sup>®</sup> ) 25mg/ml solution for injection	In stock	Cannot support an uplift in demand

8. 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.
9. 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<sup>®</sup>) 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.
10. 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.
11. [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.

**Table 2: Available alternative sedating antihistamines\***

Alternative sedating antihistamine	Available presentations	Licensed indications
Alimemazine	10mg tablets	<ul style="list-style-type: none"> <li>• Management of urticaria and pruritus.</li> <li>• In children aged 2-7 years: Pre-medication sedation before general anaesthesia.</li> </ul>
	10mg/5ml oral solution	
	7.5mg/5ml oral solution	
	30mg/5ml oral solution	
Cinnarizine	15mg tablets	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Control of motion sickness.</li> </ul>
Cinnarizine with dimenhydrinate	Arlevert <sup>®</sup> tablets	Treatment of vertigo symptoms of various origin in adults.
Chlorphenamine	4mg tablets	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Symptomatic relief of itch associated with chickenpox.</li> </ul>
	2mg/5ml oral solution	
Cyproheptadine hydrochloride	Periactin <sup>®</sup> 4mg tablets	<ul style="list-style-type: none"> <li>• Acute and chronic allergic and pruritic conditions.</li> <li>• Adjunctive therapy to adrenaline and other standard measures for the relief of anaphylactic reactions after the acute manifestations have been controlled.</li> </ul>
Cyclizine	50mg tablets	Prevention and treatment of nausea and vomiting in adults and children aged 6 years and over.
Diphenhydramine	25mg tablets	<ul style="list-style-type: none"> <li>• An aid to the relief of temporary sleep disturbance.</li> <li>• Histergan brand also licensed for treatment of allergic conditions</li> </ul>
	50mg tablets	
Hydroxyzine	10mg tablets	<ul style="list-style-type: none"> <li>• Symptomatic treatment of anxiety in adults.</li> <li>• Symptomatic treatment of pruritus associated with urticaria in adults, adolescents and children (≥5-11 years).</li> </ul>
	25mg tablets	
Ketotifen	Zaditen <sup>®</sup> 1mg tablets	<ul style="list-style-type: none"> <li>• Symptomatic treatment of allergic conditions including rhinitis and conjunctivitis.</li> </ul>
	Zaditen <sup>®</sup> 1mg/5ml elixir	

\*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

Please refer to the SmPC's for information on alternative preparations:

- [Alimemazine SmPC](#)
- [Cinnarizine SmPC](#)
- [Cinnarizine with dimenhydrinate SmPC](#)
- [Chlorphenamine SmPC](#)
- [Cyproheptadine hydrochloride SmPC](#)
- [Cyclizine SmPC](#)
- [Diphenhydramine SmPC](#)
- [Histergan \(diphenhydramine\) SmPC](#)
- [Hydroxyzine SmPC](#)
- [Ketotifen SmPC](#)
- [Promethazine SmPC](#)

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](#)

Guidance on ordering and prescribing unlicensed imports

12. 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

13. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Board 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)

**Specialist Pharmacy Service (SPS) website**

14. The UK Department of Health and Social Care (DHSC) in conjunction with the NHS Specialist Pharmacy Service (SPS) have launched an online Medicines Supply Tool, which provides up to date information about medicine supply issues.

15. To access the online Medicines Supply Tool it is required to register with the [SPS website](#). Registration for access to the website is available to UK healthcare professionals and organisations providing NHS healthcare. The tool is located under the Planning tab and then click on Medicines Supply option.

16. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool in order to stay up to date with regards to medicines supply disruptions.

17. Please be aware that while medicines supply issues will appear on the SPS website, some of the recommended actions may not be appropriate / relevant within the Scottish context.

**Enquiries**

18. Enquiries from Health Boards or healthcare professionals should be directed in the first instance to [PharmacyTeam@gov.scot](mailto:PharmacyTeam@gov.scot) (primary care) or [NSS.NHSSMedicineShortages@nhs.scot](mailto:NSS.NHSSMedicineShortages@nhs.scot) (secondary care).