



Medicine Supply Notification

MSN/2022/060

Promethazine hydrochloride 25mg tablets

Tier 2 – medium impact*

Date of issue: 06/07/2022

Link: [Medicines Supply Tool](#)

Summary

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

Actions Required

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 supporting 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 supporting information); and
- if the options suggested in this MSN 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 supporting 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 supporting 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 supporting information).

*Classification of Tiers can be found at the following link:

<https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/>

Supporting information

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.

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 [®]) 20mg tablets	In stock	Can support a small uplift in demand
Promethazine teoclate 25mg tablets (brands include Careway nausea relief [®] , Avomine [®] , LLOYDSPHARMACY travel sickness and nausea [®])	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 [®]) 5mg/5ml elixir	In stock	Cannot support an uplift in demand
Promethazine hydrochloride (Phenergan [®]) 25mg/ml solution for injection	In stock	Cannot support an uplift in demand

Table 2: Available alternative sedating antihistamines*

Alternative sedating antihistamine	Available presentations	Licensed indications
Alimemazine	10mg tablets	<ul style="list-style-type: none"> • Management of urticaria and pruritus. • In children aged 2-7 years: Pre-medication sedation before general anaesthesia.
	10mg/5ml oral solution	
	7.5mg/5ml oral solution	
	30mg/5ml oral solution	
Cinnarizine	15mg tablets	<ul style="list-style-type: none"> • 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	Arlevert® tablets	Treatment of vertigo symptoms of various origin in adults.
Chlorphenamine	4mg tablets	<ul style="list-style-type: none"> • 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.
	2mg/5ml oral solution	
Cyproheptadine hydrochloride	Periactin® 4mg tablets	<ul style="list-style-type: none"> • 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	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"> • An aid to the relief of temporary sleep disturbance. • Histergan brand also licensed for treatment of allergic conditions
	50mg tablets	
Hydroxyzine	10mg tablets	<ul style="list-style-type: none"> • Symptomatic treatment of anxiety in adults. • Symptomatic treatment of pruritus associated with urticaria in adults, adolescents and children (≥5-11 years).
	25mg tablets	
Ketotifen	Zaditen® 1mg tablets	<ul style="list-style-type: none"> • Symptomatic treatment of allergic conditions including rhinitis and conjunctivitis.
	Zaditen® 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:

[Alimenazine 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

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:

- [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:
 - 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**”.

Enquiries

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