



Medicine Supply Notification

MSN/2022/085

Prochlorperazine (Stemetil®) 5mg/5ml Syrup

Tier 2 – medium impact*

Date of issue: 12/10/2022

Link: [Medicines Supply Tool](#)

Summary

- All batches of Stemetil 5mg/5ml Syrup have been recalled as a precautionary measure due to the identification of N-nitrosomethylphenylamine (NMPA) above the acceptable limit.
- A recall notice has been published on the Medicine and Healthcare products Regulatory Agency website: [Class 2 Medicines Recall: Aventis Pharma Limited \(t/a Sanofi\), Stemetil 5mg/5ml Syrup, EL \(22\)A/41 - GOV.UK](#) (www.gov.uk)
- There will be no further production of Stemetil 5mg/5ml Syrup, so this is in effect a product discontinuation and supplies are no longer available.
- Prochlorperazine tablets and buccal tablets remain available and can support a full uplift in demand.
- Alternative antiemetics are also available and can support a full uplift in demand.

Actions Required

Clinicians in primary and secondary care should:

- not initiate patients on prochlorperazine (Stemetil®) 5mg/5ml Syrup;
- review if patients can swallow solid dosage forms and switch to prochlorperazine tablets if possible, or
- switch to prochlorperazine 3 mg buccal tablets, where appropriate, if patients cannot swallow a tablet whole or;
- review those patients in whom a liquid is preferred for consideration of suitability of an alternative antiemetic available as a liquid formulation; or
- assess ability of patient/carer to crush and disperse prochlorperazine tablets in water (unlicensed) to deliver a whole or part dose, if above options are not considered appropriate.

See Supporting Information section for further information on therapeutic alternatives.

*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

Prochlorperazine syrup is licenced for treatment of vertigo due to Meniere's syndrome, labyrinthitis and other causes, and for nausea and vomiting from whatever cause including that associated with migraine. It is not recommended for use in children weighing less than 10 kg or below 1 year of age.

Therapeutic alternatives

Prochlorperazine 5mg tablets

Identical licensed indications to that of prochlorperazine syrup.

Prochlorperazine 3mg buccal tablets

Identical licensed indications to that of prochlorperazine syrup but differ in that they are only approved for use in adults and children aged 12 years and over. The tablet is placed in the buccal cavity, high up along the top gum under the upper lip, until dissolved.

If these are not suitable, the following are antiemetics available as liquid formulations. Care should be taken when prescribing because they differ in licensed indications and licensed age groups.

Promethazine (Phenergan) Elixir 5 mg/5 ml

Licensed as an antiemetic in adults and children from the age of 2 years.

Ondansetron 4mg/5ml Syrup

Licensed in adults for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy, and for the prevention of post-operative nausea and vomiting; and in children aged ≥ 6 months for the management of chemotherapy-induced nausea and vomiting.

Metoclopramide 5mg/5ml Oral Solution

Licensed in adults for the prevention of delayed chemotherapy induced nausea and vomiting; of radiotherapy induced nausea and vomiting; and the symptomatic treatment of nausea and vomiting, including that associated with acute migraine.

It is only licensed as a second line option in children aged from 1 year for prevention of delayed chemotherapy induced nausea and vomiting.

Unlicensed manipulation of prochlorperazine 5mg tablets

For patients requiring prochlorperazine, who are unable to swallow a solid dosage form or use (or are unsuitable for) the buccal formulation, NEWT guidelines suggest that the tablets can be crushed and mixed with water for administration. A part dose will have to be extracted from the dispersion for dosages less than 5mg. If part doses are required, patients should be counselled on the steps to take to make up the appropriate dose. This is an unlicensed use of the product.

Please see the following links for further information:

[BNF: Nausea and labyrinth disorders](#)

[SmPC: Prochlorperazine 5mg tablets](#)

[SmPC: Prochlorperazine 3mg buccal tablets](#)

[SmPC: Promethazine \(Phenergan\) Elixir 5 mg/5 ml Oral Solution](#)

[SmPC: Ondansetron 4mg/5ml Syrup](#)

[SmPC: Metoclopramide 5mg/5ml Oral Solution](#)

Enquiries

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