

EMLc

Codes ATC: R06AD02

|                              |  |
|------------------------------|--|
| Indication                   | Nausea or vomiting<br>Code ICD11: <b>MG10</b>  |
| INN                          | Promethazine   |
| Type de médicament           | Chemical agent   |
| Type de liste                | Liste de base (EML)<br>(EMLc)  |
| Additional notes             | Contraindicated in children under 2 years.   |
| Formulations                 | Oral > Liquid: 5 mg per 5 mL (hydrochloride)<br>Oral > Solid: 10 mg (hydrochloride) ; 25 mg (hydrochloride)<br>Parenteral > General injections > unspecified: 25 mg per mL in 2 mL ampoule                     |
| Historique des statuts LME   | Ajouté pour la première fois en 1977 ( <b>TRS 615</b> )<br>Modifié en 1979 ( <b>TRS 641</b> )<br>Modifié en 2003 ( <b>TRS 920</b> )<br>Modifié en 2007 ( <b>TRS 950</b> )<br>Retiré en 2009 ( <b>TRS 958</b> ) |
| Sexe                         | Tous   |
| Âge                          | Aussi recommandé pour les enfants  |
| Équivalence thérapeutique    | La recommandation concerne ce médicament spécifique  |
| Renseignements sur le brevet | Patents have expired in most jurisdictions<br>Lire la suite <a href="#">sur les brevets.</a>   |
| Wikipédia                    | <a href="#">Promethazine</a>   |
| DrugBank                     | <a href="#">Promethazine</a>   |

## Résumé des preuves et recommandation du comité d'experts

A review of the use of antiemetics in children, particularly for the treatment of postoperative nausea and vomiting (PONV), was prepared by the Discipline of Clinical Pharmacology, University of Newcastle, Australia, following a request by the 2nd Subcommittee. Expert reviews of the submission were prepared by Dr Marcus Reidenberg and Mrs Jehan Al-Fannah. The Committee noted that data summarized in the submission showed that, of the antiemetics available, those with the greatest evidence of efficacy in the prevention of PONV were ondansetron and dexamethasone. The use of promethazine in treatment of PONV was not supported by any published data. The Committee noted the guidelines from the Society for Ambulatory Anesthesia (SAMBA) (1) that recommend ondansetron as first-line treatment for prevention of PONV, with the addition of dexamethasone as required. Metoclopramide and promethazine are not currently recommended. The Committee recognized that all the medicines for the prevention of PONV have age restrictions on use, with the exception of ondansetron which is licensed for use in children older than 1 month by the US Food and Drug Administration (FDA). Droperidol has a black box warning from the FDA due to its association with adverse cardiovascular effects (1). One review of trials in children showed a relative risk of 1.15 to 1.66 for adverse effects with droperidol; the higher risks are associated with higher doses and longer exposure (2). The Committee recommended the inclusion of ondansetron with a square box symbol and dexamethasone as an antiemetic on both the EML and EMLc. It recommended the retention of metoclopramide as an antiemetic for children. It recommended that promethazine be deleted from the EML and EMLc due to lack of efficacy in PONV. The Committee also noted that H1 blockers are effective for

motion sickness, but did not consider this to be a public health priority. References: 1. Gan TJ et al. Society for Ambulatory Anesthesia Guidelines for the management of postoperative nausea and vomiting. *Ambulatory Anesthesiology*, 2007, 105:1615–1628. 2. Henzi I, Sonderegger T, Tramer MR. Efficacy, dose-response, and adverse effects of droperidol for prevention of postoperative nausea and vomiting. *Canadian Journal of Anaesthesia*, 2000:537–551.

