Promethazine

NOT RECOMMENDED AS AN ESSENTIAL MEDICINE

Section: 17. Gastrointestinal medicines > 17.2. Antiemetic medicines

EMLc | ATC codes: R06AD02

Indication	Nausea or vomiting ICD11 code: MD90
INN	Promethazine
Medicine type	Chemical agent
List type	Core
Additional notes	Contraindicated in children under 2 years.
Formulations	**Oral > Liquid:** 5 mg per 5 mL (hydrochloride) **Oral > Solid:** 10 mg (hydrochloride) ; 25 mg (hydrochloride) **Parenteral > General injections > unspecified:** 25 mg per mL in 2 mL ampoule
EML status history	First added in 1977 (TRS 615) Changed in 1979 (TRS 641) Changed in 2003 (TRS 920) Changed in 2007 (TRS 950) Removed in 2009 (TRS 958)
Sex	All
Age	Also recommended for children
Therapeutic alternatives	The recommendation is for this specific medicine
Patent information	Patents have expired in most jurisdictions Read more about patents.
Wikipedia	Promethazine
DrugBank	Promethazine

Summary of evidence and Expert Committee recommendations

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. Effi cacy, dose-response, and adverse effects of droperidol for prevention of postoperative nausea and vomiting. Canadian Journal of Anaesthesia, 2000:537–551.

