

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

EMETROL (oral solution)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

EMETROL is a phosphorated carbohydrate solution.

Each 5 mL solution contains:

Sucrose	3,770 g
Phosphoric acid 85 %	0,025 g
PRESERVATIVE: Methyl hydroxybenzoate	0,126 % <i>m/v</i>

Contains sugar: Sucrose

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.

Clear bright, yellow-green syrupy liquid, with a peppermint odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

EMETROL is indicated for the symptomatic relief of nausea associated with gastrointestinal disorder, motion sickness and morning sickness in early pregnancy.

4.2 Posology and method of administration

Posology

Adults: Two (2) to four (4) medicine measures (10 to 20 mL) initially. Repeat every 15 minutes until distress subsides. Do not exceed five (5) doses in one hour.

Children over 3 years of age: One (1) to two (2) medicine measures (5 to 10 mL) initially. Repeat every 15 minutes until distress subsides. Do not exceed five (5) doses in one hour.

Motion sickness (car, air, etc.):

Adults: Three (3) to six (6) medicine measures (15 to 30 mL). Repeat every 15 minutes until distress subsides. Do not exceed five (5) doses in one hour.

Morning sickness: Three (3) to six (6) medicine measures (15 to 30 mL). Dose should be taken on arising and repeated every three hours when needed.

Method of administration

For oral use. Do not dilute since the optimal pH for functioning will be destroyed. Oral fluids should not be taken immediately before or for at least 15 minutes after the dose (see section 4.4).

4.3 Contraindications

- EMETROL is contraindicated in patients with known hypersensitivity to sucrose, phosphoric acid or any of the excipients listed in section 6.1.
- EMETROL should not be given to patients suffering from renal failure, diabetes, and hereditary fructose intolerance.

4.4 Special warnings and precautions for use

EMETROL should not be taken for more than 1 hour (5 doses) without consulting a doctor. If nausea continues or recurs, consult a doctor since this may be a sign of a serious condition.

Fluids must not be taken immediately prior to or for at least 15 minutes after a dosage of EMETROL, because of the diluting effect (see section 4.2).

Sucrose warning:

EMETROL contains sucrose which may influence the glycaemia control of patients with diabetes mellitus. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltose insufficiency should not take EMETROL.

Methyl hydroxybenzoate warning:

EMETROL contains methyl hydroxybenzoate as preservative. It may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential/ Contraception in males and females

No information available.

Pregnancy

No information available.

Breastfeeding

No information available.

Fertility

No information available.

4.7 Effects on ability to drive and use machines

EMETROL has no or negligible influence on mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision.

4.8 Undesirable effects

EMETROL produces no side effects.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety x SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

In addition, side effects can also be reported to info@pharmacorp.co.za.

4.9 Overdose

Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

5.7.2 Anti-emetics and antivertigo preparation.

Mechanism of action:

EMETROL has anti-emetic properties.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol (E 422)

Methyl hydroxybenzoate (preservative) (E 218)

Peppermint oil (F1102)

Spearmint oil (401410HR)

Methyl salicylate

FD & C Green no 3 (CI 42053, E 143)

FD & C Yellow no 10 (CI 47005, E 104)

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 °C, and out of direct sunlight.

Do not refrigerate.

6.5 Nature and contents of container

Amber, generic glass bottles of 100 mL and 200 mL.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product.

No special precautions.

7 THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACORP (PTY) LTD

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Irene, 0178

Pretoria, RSA

8 REGISTRATION NUMBER

C/5.7.2/968

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22 September 1994

10 DATE OF REVISION OF TEXT

26 September 2025