PROFESSIONAL INFORMATION

EMEX

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

EMEX (3,0 g/5 mL syrup)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL syrup contains invert sugar 3,0 g.

Contains sugar: Invert sugar (dextrose and fructose) 3,0 g

Contains preservative: Methylparaben 0,1 % *m/v*

For the full list of excipients, see **section 6.1**

3 PHARMACEUTICAL FORM

A colourless to slightly opalescent spearmint flavoured syrup.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

EMEX is indicated for the symptomatic relief of nausea in motion sickness and in early pregnancy.

4.2 Posology and method of administration

Posology

Motion sickness (car, air, etc.):

Adults: Three to six (15 to 30 mL) medicine measures. Dose may be repeated every fifteen minutes until distress subsides but should not be taken for more than one hour (five doses) without consulting a doctor.

Children over 3 years of age: One to two (5 to 10 mL) medicine measures. Dose may be repeated every fifteen minutes until distress subsides but should not be taken for more than one hour (five doses) without consulting a doctor.

Morning sickness:

Three to six (15 to 30 mL) medicine measures. Dose should be taken on arising and repeated every three hours as needed.

Paediatric population

Children under 3 years of age: Use is not recommended.

Method of administration

Do not dilute the dosage 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.

4.3 Contraindications

EMEX should not be used in:

- Patients suffering from methyl alcohol poisoning
- Renal failure
- Diabetes
- Hereditary fructose intolerance.

4.4 Special warnings and precautions for use

EMEX syrup must not be taken for more than 1 hour (5 doses) without consulting a doctor. If nausea continues or recurs frequently, consult a physician promptly 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 EMEX because of the diluting effects.

Patients with rare hereditary problems of fructose intolerance or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

EMEX is not known to interact with other medicines. No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

There are no data on fertility, pregnancy and lactation.

4.7 Effects on ability to drive and use machines

EMEX has no effect on the ability to drive and use machines.

4.8 Undesirable effects

EMEX 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. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 and to Cipla Medpro (Pty) Ltd at drugsafetysa@cipla.com or telephone 080 222 6662 (toll free).

4.9 Overdose

EMEX is a safe and non-toxic medicine.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A.5.7.2 Anti-emetics and anti-vertigo preparations.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Methylhydroxybenzoate (methylparaben)
- Phosphoric acid
- Spearmint LR21774
- Water.

6.2 Incompatibilities

This medicine must not be mixed with other medicines.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 °C, at ambient conditions of humidity.

6.5 Nature and content of container

EMEX is packed in 100 mL or 200 mL medical round amber bottles made from type III soda glass with 28 mm white polypropylene cap or 28 mm duet medprop cap.

6.6 Special precautions for disposal and other handling

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

CIPLA MEDPRO (PTY) LTD

Building 9

Parc Du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

8 REGISTRATION NUMBER

W/5.7.2/205

9 DATE OF FIRST AUTHORISATION

12 July 1990

10 DATE OF REVISION OF THE TEXT

21 November 2022