Module 1.3.1.1.2 Professional Information (PI) – Clean

PROFFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

1. NAME OF THE MEDICINE

PNEUCID (solution)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 25 mL solution contains:

Sodium citrate dihydrate 2,5 g

Citric acid monohydrate 1,65 g

Benzoic acid (preservative) 0,1 % *m/v*

Contains sugar: Sorbitol 70 % solution 2,3550 g per 25 mL

Contains sweetener: Sodium saccharin 0,0075 g per 25 mL

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solutions

Colourless, slightly turbid solution, free from any visible particles, with a sweet / sour / aniseed taste.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

PNEUCID is an antacid which may be given before anaesthesia to increase the gastric pH.

4.2 Posology and method of administration

Posology

The recommended adult dosage is 25 – 30 mL orally.

Paediatric population

The safety and efficacy of PNEUCID in children has not been established.

Method of administration

PNEUCID solution should be given within one hour to proposed anaesthetic and may be given immediately before induction.

Shake the bottle before use.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Should not be given concomitantly with aluminium based antacids (see section 4.5).

Caution is advised in patients with:

- abnormal renal function to avoid development of alkalosis.
- sodium-restricted diets.

Excipients with known effect

PNEUCID contains sorbitol 70 % equivalent to 2 355 mg/25 mL sorbitol.

The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account.

Patients with hereditary fructose intolerance (HFI) should not take/be given PNEUCID.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

PNEUCID contains 41 mg alcohol (ethanol) in each dosage unit, which is equivalent to 34 mg/25 ml (0,1 % *w/v*). The amount in 30 ml (max dose) of this medicine is equivalent to less than 1,0 ml beer or 0,4 ml wine.

4.5 Interaction with other medicinal products and other forms of interaction

PNEUCID should not be given with aluminium based antacids (see “Warnings”).

The content of sorbitol in medicines for oral use may affect the bioavailability of other medicines for oral use administered concomitantly.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety during pregnancy has not been established.

Breastfeeding

Safety during lactation has not been established.

Fertility

No data available.

4.7 Effects on ability to drive and use machines

PNEUCID has negligible effect on the ability to drive or to use machines.

4.8 Undesirable effects

PNEUCID is generally well tolerated without any unpleasant side effects when given in the recommended doses to patients with normal renal function.

Caution is advised in patients with abnormal renal function to avoid development of alkalosis (see section 4.4).

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 requested 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.

4.9 Overdose

Overdosage may result in metabolic alkalosis requiring symptomatic and supportive treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 11.4.1 Acid neutralisers.

Pharmacological action

PNEUCID is a clear, non-particulate, oral acid neutralising solution. Each 25 mL (supplies 0,9 mEq of acid neutralising capacity) buffers 200 mL of 0,1 mol.dm^3 hydrochloric acid solution to pH 2,95.

5.2 Pharmacokinetic properties

Sodium citrate and citric acid:

Citrates are oxidized in the body to form sodium bicarbonate. This is eliminated via the urine and less than 5 % is excreted unchanged.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chloroform

Terpeneless lemon oil

Anise oil

Alcohol 96%

Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 ºC in a dry place.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Single dose units of 25 ml in a brown PVC bottle with a white PP screw-on cap, or

Single dose units of 25 ml in a brown PET bottle with a white, tamper evident, HDPE screw-on cap.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

MDI Healthcare CC

374 Anderson Street

Menlo Park

0081

Tel: 012 460 1525

8. REGISTRATION NUMBER

Y/11.4.1/309

9. DATE OF FIRST AUTHORISATION

Date of registration: 17 August 1992

10. DATE OF REVISION OF TEXT

28 January 2026

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