SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Citrate 0.3 M Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium citrate

2.647 g of sodium citrate in 30 ml of oral solution

Excipients with known effect:

Each 30 ml dose contains sodium (0.6 g) and glycerol (11.6 g)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Solution

The product is a clear and colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Non-particulate antacid for use by mouth prior to general anaesthesia for caesarean section.

4.2 Posology and method of administration

Posology

30 ml of a 0.3 M solution orally immediately prior to anaesthesia.

Method of administration

Oral use only.

4.3 Contraindications

Hypersensitivity to the active ingredient or to other ingredients of the product.

4.4 Special warnings and precautions for use

Sodium Citrate should not be administered to patients with metabolic or respiratory alkalosis, hypocalcaemia, or hypochlorhydria. Sodium containing salts should be administered extremely cautiously to patients with heart failure, oedema, renal impairment, hypertension, or aldosteronism. (During treatment of acidosis, frequent monitoring of serum-electrolyte concentrations and acid-base status is essential. Alkalinisation of the urine by bicarbonates or bicarbonate precursors leads to increased renal clearance of acidic drugs.) However, urinary alkalinisation prolongs the half-life of basic drugs and may result in toxicity.

Citrates and citric acid enhance intestinal aluminium absorption in renal patients which may lead to increased, harmful serum aluminium levels. It has therefore, been suggested that patients with renal failure taking aluminium compounds to control phosphate absorption should not be prescribed citrate or citric acid containing products.

This medicinal product contains 621 mg sodium per 30 ml dose, equivalent to 31% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

4.5 Interaction with other medicinal products and other forms of interaction

As with all antacids, sodium citrate may affect the absorption of many drugs.

4.6 Fertility, pregnancy and lactation

This product is indicated for use in pregnant women, prior to general anaesthesia for caesarean.

Breastfeeding

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to sodium citrate is negligible.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

There are no further effects other than those mentioned in Sections 4.3, 4.4, 4.5 and 4.9 of the Summary of Product Characteristics.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

As with all antacids, overdose may produce metabolic alkalosis. The product contains 27 mmol of sodium ions per 30 ml and this should be considered. Management of overdose should include monitoring of plasma electrolytes and acid-base status, and general supportive measures.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sodium citrate has no relevant pharmacodynamic activity other than that caused by its alkalinity (e.g. its gastric acid neutralising capacity).

5.2 Pharmacokinetic properties

Sodium citrate is systemically absorbed and renally eliminated, causing metabolic alkalosis and urine alkalisation in sufficient doses.

5.3 Preclinical safety data

No further data is provided.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water

Glycerol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Do not store above 25°C.

Store in the original bottle in order to protect from light. Keep the bottle tightly closed.

For single use only. Discard any remaining solution.

6.5 Nature and contents of container

Amber PET 30 ml bottle with a tamper evident HDPE cap with a LDPE liner.

Packs of 1 or 10 bottles per carton.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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TS21 3FD

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8 MARKETING AUTHORISATION NUMBER(S)

PL 48259/0056

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/12/2022

10 DATE OF REVISION OF THE TEXT

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