# SUMMARY OF PRODUCT CHARACTERISTICS

**Product Summary**

## 1. NAME OF THE MEDICINAL PRODUCT

Sodium Citrate 0.3M Oral Solution

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Citrate
2.647g of Sodium Citrate in 30ml of Oral Solution

For excipients see 6.1 below

## 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 to prior to general anaesthesia for caesarean section.

### 4.2. Posology and method of administration

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

### 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.

**4.5. Interactions with other medicinal products and other forms of interaction**

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

**4.6. Pregnancy and lactation**

Use as indicated above

**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.

**4.9. Overdose**

As with all antacids, overdose may produce metabolic alkalosis. The product contains 27mmol of Sodium ions per 30ml 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 and Glycerol

**6.2. Incompatibilities**

Not applicable

**6.3. Shelf life**

2 years

**6.4. Special precautions for storage**

Do not store above 25°C. Store in the original container. Keep the container tightly closed. For single use only. Discard any remaining solution.

**6.5. Nature and contents of container**

Amber PET bottle with LDPE-lined closure.

**6.6. Instruction for use and handling**

None

**Administrative Data**

**7. LEGAL CATEGORY**
POM

**8. MARKETING AUTHORISATION HOLDER**
Viridian Pharma Ltd
Yew Tree House, Hendrew Lane, Llandevaud, Newport, Gwent NP18 2AB

**9. MARKETING AUTHORISATION NUMBER**
20346/0001

**10. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**
September 2005

**11. DATE OF REVISION OF THE TEXT**
December 2007