1. Name of the medicinal product

KALSEMAX CALCIUM SUSPENSION

2. Qualitative and quantitative composition

Each 5 ml contains:

Calcium Carbonate B.P	
(as CALCIUM)	150mg
Magnesium Hydroxide B.P.	
(as MAGNESIUM)	25mg
Zinc Sulphate B.P	
(as ZINC)	1.5mg
Vitamin D3 B.P	200I.U

3. Pharmaceutical form

Oral Suspension
Gluten and Sugar free.

4. Clinical particulars

4.1 Therapeutic indications

Kalsemax alleviates the painful conditions resulting from the reflux of gastric acid and bile into the oesophagus by suppressing the reflux itself. It is indicated in heartburn, including heartburn of pregnancy, dyspepsia associated with gastric reflux, hiatus hernia, reflux oesophagitis, regurgitation and all cases of epigastric and retrosternal distress where the underlying cause is gastric reflux.

4.2 Posology and method of administration

For oral administration
Adults and children over 12 years: Two to four 5 ml spoonfuls.

Doses should be taken after meals and at bedtime.

Children under 12 years: Should be given only on medical advice.
Elderly: No dosage modification is required in this age group.

Hepatic Impairment: No dose modification necessary.

Renal Insufficiency: Caution if highly restricted salt diet is necessary (see section 4.4).

4.3 Contraindications

This medicinal product is contraindicated in patients with known or suspected hypersensitivity to the active substances or to any of the excipients listed in section 6.1, including ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216) and butyl parahydroxybenzoate (see section 4.4).

4.4 Special warnings and precautions for use

Kalsemax should not be taken within 1 to 2 hours of taking other medicines by mouth, or for more than 2 weeks if symptomspersist.
If symptoms do not improve after seven days, the clinical situation should be reviewed.
This medicinal product contains 286.5 mg (12.45 mmol) sodium per 20 ml dose, equivalent to 14.3 % of the WHO recommended maximum daily intake for sodium. The maximum daily dose of this product is equivalent to 57.2 % of the WHO recommended maximum daily intake for sodium. This product is considered high in sodium. This should be particularly taken into account for those on a low salt diet (e.g. in some cases of congestive heart failure and renal impairment).
Each 10 ml dose contains 160 mg (1.6 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.
Kalsemax should not be used by patients allergic to any of its constituents.
Ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoates (E216) and butyl parahydroxybenzoate: may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

A time-interval of 2 hours should be considered between Kalsemax Liquid intake and the administration of other medicinal products, especially tetracyclines, digoxine, fluoroquinolone, iron salt, ketoconazole, neuroleptics, thyroid hormones, penicillamine, beta-blockers (atenolol, metoprolol, propanolol), glucocorticoid, chloroquine and biphosphonates (diphosphonates) and estramustine. See also 4.4.
Antacids may interact with other drugs as they alter the gastric pH which may affect dissolution, solubility or ionisation of the other drug. Antacids reduce the absorption of certain drugs from the following groups: ACE Inhibitors, Analgesics, Antibacterials, Antiepileptics, Antifungals, Antimalarials, Antipsychotics, Bisphosphonates, Lithium and Penicillamine.

Antacids may increase the pH of the urine and affect the rate of drug elimination. Excretion of basic drugs is decreased whereas acidic drugs are eliminated more rapidly.
Due to effects at the renal level sodium bicarbonate may reduce plasma lithium levels and increase plasma quinidine levels.

4.6 Pregnancy and lactation

Pregnancy:
Clinical studies in more than 500 pregnant women as well as a large amount of data from postmarketing experience indicate no malformative nor feto / neonatal toxicity of the active substances. Kalsemax can be used during pregnancy, if clinically needed.
Breast feeding:
No effects of the active substances have been shown in breastfed newborns/infants of treated mothers. Kalsemax can be used during breast-feeding.
Fertility:
Pre-clinical investigations have revealed alginate has no negative effect on parental or offspring fertility or reproduction.

Clinical data do not suggest that Kalsemax has an effect on human fertility.

4.7 Effects on ability to drive and use machines

There are no effects on ability to drive or use machines.

4.8 Undesirable effects

. Adverse reactions have been ranked under headings of frequency using the following convention: very common (1/10), common (1/100 and <1/10), uncommon (1/1000 and <1/100), rare (1/10,000 and <1/1000), very rare (< 1/10,000) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse Event
Immune System Disorders	Very rare	Anaphylactic and anaphylactoid reactions. Hypersensitivity reactions such as urticaria.
Respiratory, Thoracic and Mediastinal Disorders	Very rare	Respiratory effects such as bronchospasm.

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

Symptoms
As Kalsemax mode of action is physical, overdosage in terms of the alginate content is virtually no hazard. The only consequence is abdominal discomfort which is best treated conservatively. The relatively low concentrations of sodium and calcium carbonate in Kalsemax would also make serious consequences from overdosage very unlikely.
Management
In the event of overdose symptomatic treatment should be given.

5. Pharmacological properties

5.1 Pharmacodynamic properties

On ingestion the product reacts rapidly with gastric acid to form a raft of alginic acid gel having a near neutral pH and which floats on the stomach contents, quickly and effectively impeding gastro-oesophageal reflux, for up to 4 hours. In severe cases the raft itself may be refluxed into the oesophagus, in preference to the stomach contents, and exert a demulcent effect.

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber in addition to that included in other sections of the SmPC.

6. Pharmaceutical particulars

6.1 List of excipients

Carbomer
Sodium Hydroxide

Saccharin Sodium

Ethyl parahydroxybenzoate (E214)
Propyl parahydroxybenzoate (E216)

Butyl parahydroxybenzoate

Isopropyl Alcohol

Peppermint Oil

Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months - amber glass bottles

18 months - HDPE bottles

12 months - PET bottles

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze.

6.5 Nature and contents of container

Pharmaceutical Grade III amber glass bottles with pilfer proof caps and tamper evident screw caps.

High density polyethylene bottles with tamper evident screw caps.

PET bottles with tamper evident screw caps.
Pack sizes: 100ml, 150ml, 200ml, 250ml, 300ml and 500ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing authorisation holder

Mfg. by: Company Name: Nalis Pharmaceuticals Limited
Plot R67/68 Nekede-Naze industrial Cluster, Nekede,Owerri-Nigeria. OR 11 Budland Street Akiode Ojodu-Berger Ikeja, Lagos-Nigeria.

Mfg. for:
STERLING BIOPHARMA LTD
6 Femi Asiwaju Close, Ojodu, Lagos