SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

GASTICA SUSPENSION (Simethicone Emulsion, Calcium Carbonate, Magnesium
Hydroxide & Magnesium Trisilicate Suspension)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml. (one teaspoonful) Contains:

Simethicone Emulsion (30%) USP	83 mg
Calcium Carbonate BP	400 mg
Magnesium Hydroxide BP	120 mg
Magnesium Trisilicate BP	50 mg
Flavoured base	QS

3. PHARMACEUTICAL FORM

Suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

GASTICA Suspension is used for relief of
-Acidity
-Indigestion
-Heart burn
-Flatulence

4.2 Posology and method of administration Method of administration: Oral Posology:

Two teaspoonfuls (10 ml) to be taken ½ - 1 hour after meals or as directed by the physician.

4.3 Contraindications

GASTICA Suspension is contraindicated in those patients who have shown hypersensitivity to any of the ingredients used in GASTICA Suspension.

4.4 Special warnings and precautions for use

GASTICA Suspension should be given with caution to patients with renal impairment or diseases associated with hypercalcaemia. Generally GASTICA Suspension should be avoided in patient with calcium renal calculi or history of renal calculi.

4.5 Interaction with other medicinal products and other forms of interaction

-Hypercalcaemia has occurred when calcium salts are given with thiazide diuretics or vitamin D.

-Calcium enhances the effects of digitalis glycosides on the heart.

-Calcium salts reduce the absorption of a number of other drugs such as bisphosphonates fluoride, fluoroquinolones & tetracycline.

-Antacid, including magnesium salts, interact with many other drugs both by alterations in gastric pH and emptying and by formation of complexes that are not absorbed.

Interactions can be minimised by giving the antacid and any other medications 2 to 3 hours apart.

4.6 Pregnancy and Lactation

Gastica Suspension is contraindicated in pregnancy and lactation.

4.7 Effects on ability to drive and use machines Caution should be exercised during driving activity.

4.8 Undesirable effects

GASTICA Suspension at recommended dose is safe. Calcium carbonate may occasionally cause constipation. High doses or prolonged use of calcium carbonate may lead to gastric hypersecretion & acid rebound.

Magnesium hydroxide my cause diarrhoea, an effect that is dose dependent. Hypermagnesaemia may occur, usually in patient with renal impairment.

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 https://pv.pharmacyboardkenya.org

4.9 Overdose

Do not exceed the recommended dose. In case of over dosage consult the physician immediately.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacodynamics

Gastica suspension contains Simethicone Emulsion, Calcium Carbonate, Magnesium Hydroxide & Magnesium Trisilicate suspension as an active ingredient. This combination is used as Antacid and Ant flatulent.

Simethicone Emulsion works by changing the surface tension of gas bubbles in the stomach and intestines. This causes them to combine into larger bubbles that can be passed more easily. Magnesium hydroxide neutralizes gastric acidity; causes water retention in stool, producing laxative effect. Magnesium trisilicate works by increasing the pH of gastric juice via a neutralisation reaction. It also precipitates colloidal silica, which can coat gastrointestinal mucosa conferring further protection. Calcium carbonate is a basic compound that acts by neutralizing hydrochloric acid in gastric secretions. Subsequent increases in pH may inhibit the action of pepsin. An increase in bicarbonate ions and prostaglandins may also confer cytoprotective effects

5.2 Pharmacokinetic properties

Simethicone Emulsion:

Absorption: Simeticone is not absorbed from the gastrointestinal tract. Excretion: Excreted unchanged in feces.

Calcium Carbonate:

Absorption: Maximal absorption occurs at doses of 500 mg or less taken with food. Oral bioavailability depends on intestinal pH, the presence of food and dosage.

Distribution: Calcium is rapidly distributed taken up by skeletal tissues following absorption and distribution into extracellular fluids. Bone contains 99% of the body's calcium and the remaining 1% is approximately equally distributed between intracellular and extracellular fluids.

Calcium acts as a co-factor to numerous enzymes.Excretion:

Excretion: Excreted mainly in the feces. The majority of renally filtered calcium is reabsorbed in the ascending limb of the loop of Henle and the proximal and distal convoluted tubules. Also secreted by sweat glands.

Magnesium Hydroxide

Absorption: About 15%-50% of magnesium hydroxide is absorbed very slowly through the small intestine.

Distribution: The peak action and distribution of magnesium hydroxide are variable. Metabolism: Unless a patient is deficient in magnesium, very little is absorbed by the intestine. Overall, about 15%-50% of the magnesium hydroxide suspension is absorbed systemically. However, it does not undergo any metabolism as it is rapidly excreted in the urine.

Elimination: After oral administration, up to 50% of the magnesium hydroxide suspension may be absorbed as magnesium ions through the small intestines and then rapidly excreted in the urine through the kidneys. The unabsorbed drug is mainly excreted in the feces and saliva.

Magnesium Trisilicate

Absorption: The hydrated silicon dioxide formed in the stomach and passes into the intestinal track where, silica can be partly absorbed.

Distribution: The hydrated silicon dioxide formed in the stomach and passes into the intestinal track.
Elimination: Excreted in the urine.

5.3 Preclinical safety data
Not known

6. PHARMACEUTICAL PARTICULARS
6.1 List of Excipients
Sodium Methyl Paraben
Sodium Propyl Paraben
Sodium Benzoate
Guar (Delca P 225)
Arrow Gum Super
Xanthan Gum
Sorbitol Solution 70%
Sodium Saccharin
Citric Acid
Sodium Citrate
Bronopol
Enisweet EP Powder
Peppermint oil M-6509 flavour
Purified Water

6.2 Incompatibilities
Not applicable

6.3 Shelf life
24 months

6.4 Special precautions for storage Store below 30°C, at a dry place.
Protect from light.

6.5 Nature and contents of container
200 ml amber coloured pet bottle packed in a Primary Carton along with the Pack Insert.

7. MARKETING AUTHORISATION HOLDER

Star Biotech Uganda Ltd.

Plot No.78/4, Kampala Road, P.O.Box-37555, Kampala, Uganda.

8. MARKETING AUTHORISATION NUMBER
H2022/CTD8237/16530

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION
16/11/2022

10. DATE OF REVISION OF TEXT
16/11/2022