Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Catoxymag – N Suspension

2. Qualitative and quantitative composition

Each 5 ml contains:
Dried Aluminium Hydroxide BP ..... 200 mg
Magnesium Trisilicate BP..... 200 mg
Magnesium Hydroxide BP ..... 100 mg
Sodium Alginate BP ... .100 mg
Simethicone USP ..... 25 mg

3. Pharmaceutical form

Sweet, pleasant tasting, pink coloured, smooth suspension with strawberry flavour

4. Clinical particulars

4.1 Therapeutic indications

Indicated for Flatulent dyspepsia, hyperacidity, heartburn, hiatus hernia, reflux oesophagitis, gastritis

4.2 Posology and method of administration

5-10 ml. (one to two teaspoonful) diluted with water or milk, taken between meals and bedtime or whenever symptoms occur.

4.3 Contraindications

Known idiosyncrasy to any of the ingredients.

4.4 Special warnings and precautions for use

SPECIAL WARNINGS:
Magnesium hydroxide and other magnesium salts, in the presence of renal insufficiency, may cause central nervous system depression, so should not be administered to patients suffering from renal insufficiency.

PRECAUTIONS:
Aluminium may cause nausea, vomiting and constipation. Large doses can cause intestinal obstruction. Excessive or normal doses in patients with low phosphate diets may cause phosphate depletion accompanied by increased resorption and urinary excretion of calcium with the risk of osteomalacia. Osteomalacia, with chronic renal failure on high aluminium dose as a phosphate binding agent. Magnesium may cause diarrhoea. Hypermagnesaemia may occur if renal function is impaired. Magnesium hydroxide and other magnesium salts, in the presence of renal insufficiency, may cause central nervous system depression. Aluminium and magnesium may alter the absorption of other medicines from the gastro-intestinal tract if administered concomitantly.

4.5 Interaction with other medicinal products and other forms of interaction

Aluminium and magnesium may alter the absorption of other medicines from the gastro-intestinal tract if administered concomitantly.

4.6 Pregnancy and Lactation

It is advised to avoid antacid preparations in the first trimester of pregnancy.

4.7 Effects on ability to drive and use machines

None reported

4.8 Undesirable effects

None reported.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions to report any suspected adverse reactions to the National Regulatory Agents.

4.9 Overdose

There is no experience of overdosage .Treatment is symptomatic and supportive.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Both aluminium hydroxide and magnesium hydroxide reduce hyperacidity. Magnesium hydroxide has a rapid and aluminium hydroxide a prolonged antacid action. Peptic activity is inhibited through both antacids by causing elevation of the gastric pH. Aluminium hydroxide has a direct antipeptic action as well as a demulcent effect which helps protect the gastrointestinal mucosa and in this way prevents further irritation or erosion and so permits healing. Aluminium hydroxide has a mild constipating effect and magnesium hydroxide a mild laxative action; because of this balanced effect there is virtually no constipation or diarrhoea. Both antacids are non-systemic and there is virtually no risk of alkalosis developing.

Simethicone aids in the dispersion and inhibits formation of "mucus-surrounded" gas bubbles in the gastrointestinal tract. This anti-foam action is exerted by changing the surface tension of the gas bubbles so that they coalesce. This permits escape of trapped gas, which then can be eliminated through belching or though passing flatus via the rectum. Simethicone has been widely investigated and used. It has a rapid action and is non-toxic. Being physiologically inert, it has no effect on digestion and is not absorbed through the gastrointestinal mucosa. Infants have been shown to tolerate simethicone well.

By dispersing gas bubble with the anti-flatulent, contact with the gastric antacid is facilitated. Coverage of the mucosa by the antacid and demulcent agents is also improved.

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

This drug has been in the market for a long period.

6. Pharmaceutical Particulars

6.1 List of Excipients

Xanthan Gum	B.P.
Liquid Sorbitol (Non-crystallising)	B.P.
Sodium Hydroxide	B.P.
Methyl Hydroxybenzoate	B.P.
Propyl Hydroxybenzoate	B.P.
Propylene Glycol	B.P.
Guar	B.P.
Saccharin Sodium	B.P.
Bronopol	B.P.
Sodium Hypochlorite 4 % Solution	I.H.S
Menthol	B.P.
Strawberry ID 26236	I.H.S
Erythrosine C.I. 45430	I.H.S
Purified water	B.P.

6.2 Incompatibilities

Nil

6.3 Shelf-Life

36 Months

6.4 Special Precautions for storage

Shake the bottle well before use replace cap tightly after use.
Store at a temperature not exceeding 30°C.

6.5 Nature and Content of container

200 ml amber glass bottles filled with Catoxymag – N Suspension, sealed, labelled and packed in a duplex board carton.

6.6 Special precautions for disposal and other handling

NA

7. Marketing Authorization Holder

RAPTAKOS, BRETT & CO. LTD.
Dr. Annie Besant Road, Worli, Mumbai – 400 030, INDIA

8. Marketing Authorization Number
18708

9. Date of first authorization/renewal of the authorization

10. Date of revision of the text
November 2020