SUMMARY OF PRODUCT CHARACTERISTIC:

1.3 SUMMARY OF PRODUCT CHARACTERISTICS:

1. NAME OF THE MEDICINAL PRODUCT:

ALGIMET (aluminium hydroxide, magnesium hydroxide, activated dimeticone and deglycyrrhizinated liquorice gel)

2. Qualitative and Quantitative Composition

Composition:

Each 5 ml Contains:

Aluminium Hydroxide Gel BP……6 gm

Magnesium Hydroxide BP ……80 mg

Activated Dimethicone BP ……100 mg

Deglycyrrhizinated Liquorice Eq. to Liquorice BP……400 mg

Excipients……..Q.S.

Colour: permitted colour

For the full list of excipients, see section 6.1

3. Pharmaceutical Form

Liquid Dosage Form

White coloured flavoured suspension filled in transparent PET Bottle duly sealed with white colour plastic cap.

4. Clinical Particulars

4.1 Therapeutic indications

Antacid therapy in gastric and duodenal ulcer, gastritis, heartburn and gastric hyperacidity.

4.2 Posology and method of administration

Adults

5-10ml taken 20 minutes to 1 hour after meals and at bedtime or as required.

Children

As an appropriate proportion of the adult dose.

Children under 5 years

Maximum of 5ml t.d.s.

Elderly

The normal adult dose is appropriate

Method of Administration

For oral administration

4.3 Contraindications

ALGIMET should not be used in patients who are severely debilitated or suffering from renal insufficiency, or if there is severe abdominal pain and/or the possibility of bowel obstruction. Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Aluminium hydroxide may cause constipation and magnesium salts overdose may cause hypomotility of the bowel; large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at higher risk such as those with renal impairment, or the elderly. Aluminium hydroxide is not well absorbed from the gastrointestinal tract, and systemic effects are therefore rare in patients with normal renal function. However, excessive doses or long-term use, or even normal doses in patients with low-phosphorous diets, may lead to phosphate depletion (due to aluminium-phosphate binding) accompanied by increased bone resorption and hypercalciuria with the risk of osteomalacia. Medical advice is recommended in case of long-term use or in patients at risk of phosphate depletion.

In patients with renal impairment, plasma levels of both aluminium and magnesium increase. In these patients, a long-term exposure to high doses of aluminium and magnesium salts may lead to encephalopathy, dementia, microcytic anemiaor worsen dialysis-induced osteomalacia.

Aluminium hydroxide may be unsafe in patients with porphyria undergoing hemodialysis. The prolonged use of antacids in patients with renal failure should be avoided.

This product contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Paediatric population

In young children the use of magnesium hydroxide can produce a hypermagnesemia, especially if they present renal impairment or dehydration.

4.5 Interaction with other medicinal products and other forms of interaction

ALGIMET should not be taken simultaneously with other medicines as they may interfere with their absorption if taken within 1 hour.

Aluminium-containing antacids may prevent the proper absorption of drugs such as tetracyclines, vitamins, ciprofloxacin, ketoconazole, hydroxychloroquine, chloroquine, chlorpromazine, rifampicin, cefdinir, cefpodoxime, levothyroxine, rosuvastatin, H2 antagonists, atenolol,

cyclines, diflunisal, digoxin, bisphosphonates, ethambutol, fluoroquinolones, sodium fluoride, glucocorticoids, indomethacin, isoniazid, lincosamides, metoprolol, phenothiazine neuroleptics, penicillamine,propranolol and iron salts.

Levothyroxine may also bind to dimeticone which may delay or reduce the absorption of levothyroxine.

Polystyrene sulphonate

Caution is advised when used concomitantly with polystyrene sulphonate due to the potential risks of reduced effectiveness of the resin in binding potassium, of metabolic alkalosis in patients with renal failure (reported with aluminium hydroxide and magnesium hydroxide), and of intestinal obstruction (reported with aluminium hydroxide).

Quinidine:

Concomitant use of aluminium products with quinidines may increase the serum levels of quinidine and lead to quinidine overdosage.

Tetracycline:

Because of the aluminium content, ALGIMET should not be concomitantly administered with tetracycline-containing antibiotics or any tetracycline salts.

Citrates:

Aluminium hydroxide and citrates may result in increased aluminium levels, especially in patients with renal impairment.

Urine alkalinisation secondary to administration of magnesium hydroxide may modify excretion of some drugs; thus, increased excretion of salicylates has been seen.

4.6 Fertility, pregnancy and lactation

The safety of ALGIMET (Suspension) in pregnancy has not been established.

Pregnancy:

There are no available data on ALGIMET use in pregnant women. No conclusions can be drawn regarding whether or not ALGIMED is safe for use during pregnancy. ALGIMET should be used during pregnancy only if the potential benefits to the mother outweigh the potential risks, including those to the feotus.

Lactation:

Because of the limited maternal absorption, when used as recommended, minimal amounts, if any, of aluminium hydroxide and magnesium salt combinations are expected to be excreted into breast milk.

Dimeticone is not absorbed from the gastrointestinal tract.

No effect on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to aluminium hydroxide, magnesium hydroxide and dimeticone is negligible.

4.7 Effects on ability to drive and use machines

Not Known.

4.8 Undesirable effects

The following CIOMS frequency rating is used, when applicable:

Very common (≥ 1/10), common (≥ 1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), not known (cannot be estimated from available data).

Immune system disorders

Frequency not known: hypersensitivity reactions, such as pruritus, urticaria, angioedema and anaphylactic reactions

Gastrointestinal disorders

Gastrointestinal side-effects are uncommon.

Uncommon: diarrhoea or constipation (see Section 4.4)

Frequency not known: Abdominal pain

Injury, poisoning and procedural complications:

Frequency not known:

Hyperaluminemia (related to Aluminium component).

Metabolism and nutrition disorders

Very rare: Hypermagnesemia, including observations after prolonged administration of magnesium hydroxide to patients with renal impairment

Frequency not known:

Hyperaluminemia

Hypophosphatemia, in prolonged use or at high doses or even normal doses of the product in patients with low-phosphorus diets which may result in increased bone resorption hypercalciuria, osteomalacia (see section 4.4).

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 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

Serious symptoms are unlikely following overdosage.

Reported symptoms of acute overdose with aluminium hydroxide and magnesium salts combination include diarrhoea, abdominal pain, vomiting.

Large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at risk (see section 4.4)

Aluminium and magnesium are eliminated through urinary route; treatment of acute overdose consists of administration of IV Calcium Gluconate, rehydration and forced diuresis. In case of renal function deficiency, haemodialysis or peritoneal dialysis is necessary.

5. Pharmacological properties

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Drugs for acid related disorders; Antacids with antiflatulents, ATC Code: A02AF02

Dried aluminium hydroxide gel	- antacid
Magnesium Hydroxide	- antacid
Dimeticone	- antifoaming agent/antiflatulent

ALGIMETs is a balanced mixture of two antacids and an antiflatulent/antifoaming agent Dimeticone. The two antacids are magnesium hydroxide which is fast acting and aluminium hydroxide which is a slow acting antacid. The combination produces a fast onset of action and an increase in total buffering time. Aluminium hydroxide on its own is an astringent and may cause constipation. This effect is balanced by the effect of the magnesium hydroxide which is in common with other magnesium salts may cause diarrhoea.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6. Pharmaceutical particulars

6.1 List of excipients

Sorbitol Solution 70 % BP
Guar Gum BP
Sodium Methyl Hydroxybenzoate BP
Sodium Propyl Hydroxybenzoate BP
Bronopol BP
Aspartame BP
Sodium citrate BP
Sodium saccharine BP
Chloroform BP
Sodium Hydrochloride BP
Polysorbate 80 BP
Colour Titanium Dioxide BP
Flavour Peppermint IH
Peppermint Oil IH
Menthol USP

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

36 Months

6.4 Special precaution for storage

Store at temperature should not exceeding 30°C. Protect from light.

6.5 Nature and contents of container

PET Bottle contains 200 ml suspension.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7. Marketing authorisation holder

McW Healthcare Private Limited
286, 287A, 287B, Sector E, Industrial Area,
Sanwer Road, Indore (M.P.), INDIA

Algimet GEL

Size:(L)55x(W)55x(H)140mm.

Algimet GEL

200ml

Aluminium Hydroxide, Magnesium Hydroxide
Activated Dimeticone and
Deglycyrrhizinated Liquorice Gel

SJS

Antacid
Antiflatulent

Aluminium Hydroxide, Magnesium Hydroxide
Activated Dimeticone & Deglycyrrhizinated Liquorice Gel

Algimet GEL

Each 5 ml contains :

Aluminium Hydroxide Gel	BP	6gm
Magnesium Hydroxide	BP	80mg
Activated Dimeticone	BP	100mg
Deglycyrrhizinated Liquorice equivalent to Liquorice	BP	400mg
Excipients		q.s.
Colour : Permitted Colour		

DOSAGE:
One to two teaspoonfuls three to four times daily or as directed by the physician.

INDICATIONS:
Relief of pains associated with gastric acid secretion, heartburn, flatulence and indigestion.

STORAGE :
Store below 30°C.
Protect from light & moisture.

keep in a tightly closed container.
Avoid freezing.

Read the pack insert carefully.

Algimet GEL

200ml

Aluminium Hydroxide, Magnesium Hydroxide
Activated Dimeticone and
Deglycyrrhizinated Liquorice Gel

SJS

Antacid
Antiflatulent

Aluminium Hydroxide, Magnesium Hydroxide
Activated Dimeticone & Deglycyrrhizinated Liquorice Gel

Algimet GEL

KEEP THE MEDICINE OUT OF REACH OF CHILDREN.

SHAKE WELL BEFORE USE.

NAFDAC REG. No.:

Mfg. Lic. No.: **25/27/2001**

Batch No. :

Mfg. Date :

Exp. Date :

Marketed by:

SJS
Life Sciences Limited

No. 11-B, Olu Akinde Street,
IKEJA, Lagos, Nigeria-100001

Manufactured in India by:

McW Healthcare (P) Ltd.

299, 287-A, 287-B Sector E, Industrial Area,
Sanwer Road, Indore (M.P.) INDIA