1.3 Product information

1.3.1 Prescribing information (Summary of Product Characteristics (SmPC))

1. NAME OF THE MEDICINAL PRODUCT

1.1 Trade name of the medicinal product

NUGEL-O ANTACID SUSPENSION

1.2 Strength

Each 5 mL contains:

Alginic acid BP	70 mg
Dried Aluminium Hydroxide BP	85 mg
Magnesium Hydroxide BP	85 mg
Magnesium Trisilicate BP	85 mg
Simethicone BP	50 mg
Oxetacaine BP	10 mg

1.3 Pharmaceutical form

Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each 5 mL contains:

S. No.	Raw Materials	Spec.	Quantity/5mL (mg)	Functional Category
1	**Alginic Acid**	**BP**	**70.00**	**Active**
2	**Magnesium Hydroxide**	**BP**	**85.00**	**Active**
3	**Dried Aluminium Hydroxide**	**BP**	**85.00**	**Active**
4	**Magnesium Trisilicate**	**BP**	**85.00**	**Active**
5	**Simeticone**	**BP**	**50.00**	**Active**
6	**Oxetacaine**	**BP**	**10.00**	**Active**
7	Liquid Sorbitol 70 % (Non-crystallising)	BP	960.00	Vehicle
8	Propylene Glycol	BP	450.00	Co Solvent
9	Methyl Hydroxybenzoate	BP	12.50	Preservative
10	Propyl Hydroxybenzoate	BP	1.25	Preservative

11	Disodium Edetate	BP	2.50	Chelating agent
12	Saccharin Sodium	BP	6.17	Sweetening agent
13	Sodium Citrate	BP	15.00	Buffering Agent
14	Xanthan Gum	BP	22.50	Suspending Agent
15	Mentholyptus Flavour	IH	0.03 mL	Flavouring Agent
16	Erythrosine Supra	IH	0.08	Colouring Agent
17	Purified Water	BP	q.s. to 5 mL	Vehicle

3. PHARMACEUTICAL FORM

Pharmaceutical Dosage form of the product: Oral Suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For relief from ulcer, non-ulcer dyspepsia, reflux oesophagitis, heartburn and for the symptomatic relief of gastritis, flatulence, hyperacidity associated with peptic ulceration.

4.2 Posology and method of administration

Adults: 15 mL twice daily or as directed by the physician.

Children: Not to be used in children.

Method of administration:

Shake well before use. Take 20 minutes to 1 hour after meals and at bedtime or as required.

4.3 Contraindications:

Antacids 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. The use of aluminum-containing antacids (except those containing aluminum phosphates) is contraindicated in patients with hypophosphatemia due to the phosphate binding properties of aluminum salts.

The use of magnesium-containing antacids is contraindicated in patients with severe renal function impairment due to increased danger of occurrence of hypermagnesemia.

The use of aluminum- or magnesium-containing antacids is contraindicated in patients with symptoms of appendicitis since these products may increase the danger of perforation or rupture due to their constipating or laxative effects.

Should be used with caution in patients with volume depletion, gastrointestinal obstruction or upper gastrointestinal bleeding

4.4 Special warnings and precautions for use

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 dementia, microcytic anemia.

Aluminum hydroxide may be unsafe in patients with porphyria undergoing hemodialysis

4.5 Interactions with other medicinal products and other forms of interaction

The rate and/or extent of absorption of many drugs may be increased or decreased when they are used concurrently with aluminum-magnesium hydroxide containing antacids. Therefore, as a general rule, medication should not be taken within 1 to 2 hours of an antacid, if possible.

Antacids are known to interfere with the absorption of certain drugs including budesonide, aspirin, barbiturates, tetracyclines, vitamins, ciprofloxacin, ketoconazole, hydroxychloroquine, chloroquine, chlorpromazine, rifampicin, cefdinir, cefpodoxime, ACE inhibitors and β- blockers.

An increase in the plasma level of quinidine and possible toxicity may result if alkalization of the urine occurs during antacid therapy.

Antacids may interfere with drugs by increasing the gastric pH altering disintegration, dissolution, solubility, ionization and gastric emptying time.

Absorbing or binding drugs to their surface resulting in decreased bioavailability such as tetracycline.

Urinary excretion of certain drugs may also be affected.

Antacids containing magnesium salt may increase absorption of Sulphonylureas and thereby increases the hypoglycemic effect

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anaesthetic, Antacids

ATC code: A02AF

Pharmacodynamic effects

Oxetacaine produces reversible loss of sensation by preventing the conduction of sensory nerve impulses near the site of application. This acts by decreasing the permeability of the sodium ions across the membrane (membrane stabilizing effect).

In stomach it increases the pH and neutralizes the gastric acid, which relieves the hyperacidity problems.

Aluminum hydroxide and magnesium hydroxide react chemically to neutralize the existing quantities of acid by forming a coating over the inflamed mucosa but have no effect on production of gastric acid. Antacid also thickens the liquid to help carry the Oxetacaine and coat the food pipe.

5.2 Pharmacokinetic properties

The absorption of aluminium and magnesium from antacids is small. Aluminium hydroxide is slowly converted to aluminium chloride in the stomach. Some absorption of soluble aluminium salts occurs in the gastro-intestinal tract with urinary excretion. Any absorbed magnesium is likewise excreted in the urine. Aluminium containing antacids should not be administered to patients with renal impairment where increased plasma concentration may occur.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

Liquid Sorbitol 70% (Non-crystallising), Propylene Glycol, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Disodium edetate, Saccharin sodium, Sodium citrate, Xanthum Gum, Mentholyptus Flavour, Erythrosine Supra, Purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

30 months

6.4 Special precautions for storage

Store in a cool dry place, protected from light

6.5 Nature and contents of container

200 mL Amber colour glass round bottle Gold colour printing with Indus logo with EPE WAD with 10 mL measuring cup and package insert.

Material of Construction:

Bottle Packing	
Primary Packaging	200 mL Amber colour glass round bottle Gold colour printing with Indus logo with EPE WAD
Secondary Packaging	10 mL measuring cup, Carton, Printed Label & Package insert.

6.6 Special Precautions for Disposal and other Handling

No special requirements.

6.7 Marketing Authorization Holder and Manufacturing Site Addresses

MARKETING AUTHORIZATION HOLDER

INDUS LIFE SCIENCES PVT. LTD.

MANUFACTURER

SAI MIRRA INNOPHARM PVT. LTD.,
288 & 299, SIDCO Estate,
Ambattur,
Chennai - 600 098.
Tamil Nadu-India.
Tel: 91 - 44 – 4204 3221
Fax: 91(44) 2625 0470
E-mail: exports@ saimirra.com
Website: www.saimirra.com

6.8 Marketing Authorization number

6.9 Date of First Registration/Renewal of the Registration

6.10 Date of Revision of the text

6.11 Dosimetry (If applicable)

Not Applicable

6.12 Instructions for Preparation of Radiopharmaceuticals

Not Applicable

7. REGISTRANT

8. MANUFACTURER

SAI MIRRA INNOPHARM PVT. LTD.,

288 & 299, SIDCO Estate,
Ambattur,
Chennai - 600 098.
Tamil Nadu-India.
Tel: 91 - 44 – 4204 3221/ 4204 3222.
Fax: 91(44) 2625 0270
E-mail: exports@saimirra.com
Website: www.saimirra.com

9. DATE OF PUBLICATION OR REVISION

Not applicable