

Noto Sans 32pt,16pt
SemiBold

Noto Sans 8pt
Regular

Noto Sans 7pt
Bold, Regular

GASCID

suspension

Sodium Alginate 500 mg, Sodium Bicarbonate 213 mg, Calcium Carbonate 325 mg

1. Name of the medicinal product

GASCID Suspension (Sodium Alginate, Sodium Bicarbonate, Calcium Carbonate)

2. Qualitative and quantitative composition

Each 10 ml dose contains sodium alginate 0.5g, sodium bicarbonate 0.213g and calcium carbonate 0.325g.
Excipients: D-Sorbitol Solution and Saccharin Sodium Hydrate
Preservatives: Methylparaben 0.8 mg, Propylparaben 0.2 mg
For full list of excipients, see Section 6.1.

3. Pharmaceutical form

Oral suspension in sachets.

Appearance: Pale-yellow to cream colored oral suspension with peppermint flavor and it is packed aluminum pouch

4. Clinical particulars

4.1 Therapeutic indications

Treatment of symptoms resulting from the reflux of acid, bile and pepsin into the oesophagus such as acid regurgitation, heartburn and indigestion, for example following meals or during pregnancy, and for symptoms of excess stomach acid (hyperacidity). Can also be used to treat the symptoms of gastro-oesophageal reflux during concomitant treatment with or following withdrawal of acid suppressing therapy.

4.2 Posology and method of administration

For oral administration.

Adults and children 12 years and over: One to two sachets (10-20ml) after meals and at bedtime, up to four times per day.

Children under 12 years: Should be given only on medical advice.

Elderly: No dose modifications necessary for this age group.

4.3 Contraindications

Hypersensitivity to sodium alginate, sodium bicarbonate, calcium carbonate, the esters of hydroxybenzoates (parabens) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Each 10ml (single sachet) dose has a sodium content of 127.25mg (5.53mmol). This should be taken into account when a highly restricted salt diet is recommended, e.g. in some cases of congestive cardiac failure and renal impairment.

Each 10ml (single sachet) dose contains 130mg (3.25mmol) of calcium. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

Treatment of children younger than 12 years of age is not generally recommended, except on medical advice.

If symptoms persist, or treatment is required for more than seven days continuously, medical advice should be sought.

As with other antacid products, taking this product can mask the symptoms of other more serious, underlying medical conditions.

Contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

Due to the presence of calcium carbonate which act as an antacid, a time-interval of 2 hours should be considered between GASCID intake an the administration of other medicinal products, especially H2-antihistaminics tetracyclines, digoxine, fluoroquinolone, iron salt, ketoconazole, neuroleptics, thyroxine, penicilamine, beta-blockers (atenolol, metoprolol, propanolol), glucocorticoid, chloroquine, diphosphonates and estramustine.

4.6 Pregnancy and lactation

Pregnancy

Open controlled studies in 281 pregnant women did not demonstrate any significant adverse effects of GASCID on the course of pregnancy or on the health of the foetus/new-born child. Based on this and previous experience the medicinal product may be used during pregnancy, if clinically.

Breastfeeding:

No effects of the active substances have been shown in breastfed newborns/infants of treated mothers. This product can be used during breast-feeding.

Fertility:

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

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse events which have been associated with sodium alginate, sodium bicarbonate and calcium carbonate are given below, tabulated by system organ class and frequency. Frequencies are defined as:

DESIGN CONSIDERATIONS

PRODUCT NAME	Algina suspension10mL / 20 Sachets
PACKAGE	Insert
PACKAGE DECORATION	MOJO 70g / 3-8
SIZE	130*245mm
COLOR	 maximum color : 4 color
FINAL DATA CHECK	1. Create Outlines for font 2. Embed image 3. Fill in the color(used in the design) 4. Artwork format : ai(Adobe Illustration)
DATE.	23.01.26

Diecut

Design Area

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); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Events
Immune System Disorders	Very Rarely	Anaphylactic reaction, anaphylactoid reaction. Hypersensitivity reactions such as urticaria.
Metabolism and Nutritional Disorders	Not Known	Alkalosis ¹ , acid rebound ¹ , Hypercalcaemia ¹ , Milk-alkali Syndrome ¹
Respiratory, Thoracic and Mediastinal Disorders	Very Rarely	Respiratory effects such as bronchospasm.
Gastrointestinal Disorders	Not Known	Constipation ¹

Description of selected adverse reactions

¹ Usually occurs following lager than recommended dosages.

4.9 Overdose

Symptoms – Symptoms are likely to be minor in acute overdose; some abdominal distension may be noticed. Milk-alkali syndrome has occurred in individuals taking large doses of calcium carbonate per day for prolonged periods.

Management – In the event of overdosage symptomatic treatment should be given.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic classification: A02BX, other drugs for peptic ulcer and gastro-oesophageal reflux disease.

The medicinal product is a combination of two antacids (calcium carbonate and sodium bicarbonate) and an alginate.

On ingestion, the medicinal product reacts rapidly with gastric acid to form a raft of alginic acid gel having a near neutral pH and studies have shown that the raft interacts with and caps the acid pocket in the stomach, reducing oesophageal acid exposure. The raft floats on the stomach contents effectively impeding gastro-oesophageal reflux, for up to 4 hours, and protecting the oesophagus from acid, pepsin and bile. In severe cases the raft itself may be refluxed into the oesophagus, in preference to the stomach contents, and exert a demulcent effect. In addition in vitro evidence has shown that the raft has a secondary action and is able to entrap bile and pepsin within it structure, further protecting the oesophagus from these gastric components Calcium carbonate neutralises gastric acid to provide fast relief from indigestion and heartburn. This effect is increased by the addition of sodium bicarbonate which also has a neutralising action. The total neutralising capacity of the product at the lowest dose of two tablets is approximately 10mEqH⁺.

5.2 Pharmacokinetic properties

The mode of action of the medicinal product is physical and does not depend on absorption into the systemic circulation.

5.3 Preclinical safety data

No pre-clinical findings of any relevance to the prescriber have been reported.

6. Pharmaceutical particulars

6.1 List of excipients

D-Sorbitol solution, Saccharin sodium hydrate Enzymatically Modified Stevia, Steviol glucoside, Carbomer 934P, Sodium Hydroxide, Methylparaben, Propylparaben, Citrus flavor 91069, Peppermint Oil and purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

A cardboard outer carton containing unit dose stick pack style sachets.

Pack sizes: 20 and 50 sachet /Box

Not all pack sizes may be marketed.

The sachets are composed of polyester, aluminium and polyethylene.

Each sachet contains 10ml of GASCID suspension .

6.6 Special precautions for disposal and other handling

None required.

7. Manufacturer

GENUONE SCEICNES INC.

245 Sandangil, Jeoneui-myeon, Sejong-si, Republic of Korea

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