POLYGEL

(Antacid Chewable Tablets)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

POLYGEL (Antacid Chewable Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chemical Name	Approved Name (if any)	Quantity per Tablet in mg	Active / Non- active
Active Ingredients			
---	Dried Aluminium Hydroxide Gel BP	300.00	Antacid
---	Magnesium Aluminium Silicate Hydrate BP	50.00	Antacid
---	Magnesium Hydroxide BP	25.00	Antacid
poly (dimethylsiloxane)	Simethicone BP	25.00	Antifoaming Agent / Antiflatulent
Excipients			
b-D-fructofuranosyl-a-D-glucopyranoside	Sucrose (Pharma Grade) BP	384.50	Sweetening agent
D-Mannitol	Mannitol BP	267.00	Diluent
1-Ethenyl-2-pyrrolidinone homopolymer	PVP K-30 BP	12.00	Suspending Agent
Methyl-4-hydroxybenzoate	Methyl Hydroxy Benzoate BP	1.00	Antimicrobial Preservative
Propyl 4-hydroxybenzoate	Propyl Hydroxy Benzoate BP	0.500	Antimicrobial Preservative
---	Colour Erythrosine Supra IH	0.200	Colourant
1,2-Benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt	Saccharin Sodium BP	2.00	Sweetening agent
Propan-2-ol	Isopropyl Alcohol BP *	32.00	Solvent
Talc	Purified Talc BP	17.80	Glidant
Octadecanoic acid magnesium salt	Magnesium Stearate BP	13.00	Lubricant
---	Flavour Trusil Peppermint Dry Mix Powder IH	17.00	Flavouring Agent

Definitions:

* Does not appear in final product.

BP: British Pharmacopoeia, **IH:** In-house Specification

3. PHARMACEUTICAL FORM

Chewable tablet

POLYGEL

(Antacid Chewable Tablets)

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Polygel is indicated for the relief of acid indigestion, heartburn, sour stomach and symptoms of gas and stomach upset associated with those conditions. It is also indicated for the symptomatic relief of hyperacidity associated with the diagnosis of peptic ulcer, gastritis, peptic oesophagitis and hiatal hernia and as antiflatulent to alleviate the symptoms of mucus-entrapped gas, including postoperative gas pain.

4.2 Posology and method of administration

Polygel Tablets: Adults & children over 12 years: 1 - 2 Tablets; ½ to 1 hour after the meal and at bedtime or as directed by the physician. Higher doses are required for the treatment of peptic ulcer. Children: 5 - 12 years: Half the adult dose.

4.3 Contraindications

Polygel is not suitable in those patients who have shown prior history of hypersensitivity to any of the components of the drug. It is also contraindicated in patients with renal failure.

4.4 Special warnings and precautions for use

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. 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. Usage in pregnancy & lactation: Polygel is safe in pregnancy. Use in nursing mothers - Caution should be exercised when Polygel is administered to nursing mothers.

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. Polygel can reduce the activity of Fluoroquinolones, Isoniazid (oral), Iron, Indomethacin, Digoxin, Ketoconazole and Phenothiazines. Mecamylamine: Polygel may potentiate the effects of Mecamylamine. Tetracyclines: Polygel can reduce the effect of this medicine. In this case it should only be given after 3 to 4 hours of tetracycline.

4.6 Pregnancy and lactation

Usage in pregnancy & lactation: Polygel is safe in pregnancy.

Use in nursing mothers - Caution should be exercised when Polygel is administered to nursing mothers.

4.7 Adverse Reactions

The adverse effects that may be encountered with Polygel are changes in bowel function, diarrhoea being the common symptom. A small reduction in dosage may often alleviate these symptoms. Polygel

is a well-tolerated antacid. Constipation or stomach cramps, loss of appetite, vomiting, dizziness and headache may occur very rarely.

4.8 Symptoms of Overdosage & Treatment

Although unlikely, in case of use of Polygel for long periods of time if plasma aluminum concentration exceeds the safety threshold, the administration of Polygel should be discontinued. In patients without other conditions the only symptom overdose is diarrhoea. In case of severe renal impairment there may be a risk of poisoning due to magnesium, which is manifested by dry mouth, dizziness and difficulties respiratory including respiratory

depression. The treatment for overdose should consist of gastric lavage and increased intestinal transit through the use of laxatives lacking magnesium in composition. If symptoms suggestive of intoxication arising by magnesium are noticed, administration of calcium gluconate intravenously could be advised.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Polygel Tablets : **ATC Code :**A02AF02 (Antacid)

Pharmacological Category:

Dried Aluminium Hydroxide Gel BP: Antacid

Magnesium Aluminium Silicate Hydrate BP: Antacid

Magnesium Hydroxide BP: Antacid

Simethicone BP: Antifoaming Agent / Antiflatulent Agent

Pharmacological Action :

Simethicone is an antifoaming agent / Antiflatulent Agentto reduce flatulence. It is a silicon polymer that lowers surface tension & allows the small bubbles of froth to coalesce into large bubbles that can be more easily passed up from stomach or down from the colon. It is chemically inert and has no known systemic action. Aluminium hydroxide is used primarily as an antacid. Main clinical use of aluminium hydroxide is as an agent for neutralizing gastric acid. Aluminium hydroxide acts as an adsorbent of pepsin at a pH above 3. Aluminium hydroxide salts delay gastric emptying & relax gastrointestinal smooth muscle. This contributes to the constipating effect of Aluminium hydroxide. It also helps to promote a mucosal barrier to acid by stimulating mucus secretion. It interferes with phosphate absorption by forming insoluble aluminium phosphate in the gut lumen. It also inhibits the absorption of fluoride ions and binds to some fatty acids and proteins in the gut. Aluminium hydroxide appears to bind to bile acids with an affinity close to that seen with cholestyramine. Magnesium Hydroxide / Magnesium Aluminium Silicate Hydrate has laxative action and is often given with Aluminium Hydroxide gel which has a constipating action. Because of its insolubility, the antacid effect is usually prolonged over several

hours. Magnesium hydroxide increases intestinal motility. Thus Polygel contains the right balance of aluminium and magnesium compounds so as to significantly change bowel function.

5.2 Pharmacokinetic properties

Parameters	Dried Aluminium Hydroxide	Magnesium Hydroxide/ Magnesium Aluminium Silicate Hydrate	Activated Dimethicone/ Simethicone
Absorption	Poor	Poor	Poor
Plasma half life	-	-	-
Protein binding	-	-	-
Elimination	Urine	Faeces/ Urine	Faeces

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose BP, Mannitol BP, Povidone BP, Methyl Hydroxybenzoate BP, Propyl Hydroxybenzoate BP, Colour Erythrosine Supra In-House, Saccharine Sodium BP, Isopropyl Alcohol BP, Purified Talc BP, Magnesium Stearate BP and Flavour Trusil Peppermint Dry Mix Powder In-House.

6.2 Incompatibilities

None.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30°C. Protect from sunlight and moisture. Keep out of reach of children.

6.5 Nature and contents of container

POLYGEL is available as blister of 10 tablets, Such 20 blisters are packed in the carton along with leaflet.

7. MARKETING AUTHORISATION HOLDER

M/s SHALINA HEALTHCARE DMCC

Physical and Postal Address:

30th Floor, Almas Towers,

Jumeirah Lakes Towers Dubai-UAE.

Country: Dubai

8. MARKETING AUTHORISATION IN OTHER COUNTRIES

Registered in Congo, Zambia, Central African Republic.

9. DATE OF FIRST AUTHORISATION

Application for granting renewal registration certificate

10. DATE OF UPDATE OF TEXT

March 2021