GELUSIL

GELUSIL® MPS Tablets/Liquid(Original-Mint/Xtracool-Mint Flavour) Abbreviated Prescribing Information / Summary of Product Information

GENERIC NAME: Antacid Antigas Chewable Tablets/ Liquid. PRESENTATION: Dosage Form - Chewable tablets and Oral Liquid. Each uncoated chewable tablet contains: Activated Dimethicone I.P. 50 mg, Magnesium Hydroxide I.P. 250 mg, Dried Aluminium Hydroxide I.P. 250 mg, Magnesium Aluminium Silicate Hydrate 50 mg. Each 5 ml (teaspoonful) contains: Activated Dimethicone I.P. 50 mg, Magnesium Hydroxide I.P. 250 mg (added as Magnesium Hydroxide paste), Dried Aluminium Hydroxide I.P. 250 mg (added as Aluminium Hydroxide paste), Sorbitol solution (70%) I.P. (Non-Crystallising) 1.25 gm. Pack size - Tablet: 15 Tablets per blister; Original Mint Flavour Liquid: 50 ml, 200 ml, and 400 ml bottles; Xtracool Mint Flavour White: 50 ml and 200 ml bottles. INDICATION(s): Gelusil is indicated for relief of symptoms of hyperacidity (e.g., heartburn, epigastric discomfort, or their equivalents) that are often associated with dyspepsia, peptic ulcer, gastritis, peptic esophagitis, and hiatus hernia. It is also indicated for relief of atulence (gas). DOSAGE AND ADMINISTRATION: Gelusil tablets- 1-2 tablets to be chewed 30-60 min after meals or whenever symptoms are pronounced. Gelusil liquid- 1-2 teaspoonfuls (approximately 5-10 ml) 30-60 min after meals or whenever symptoms are pronounced. To achieve adequate antacid effect in the stomach at the optimum time, most antacids are administered 1 and 3 hours after meals for prolonged acid-neutralizing effect and at bedtime. Use in the Elderly- Dosing needs to be adjusted to suit individual patient requirements and characteristics. Use in Patients with Renal Impairment - Gelusil should be used with caution in patients with renal impairment. While there are no speci-c dosing recommendations for use in patients with renal impairment, dosing may need to be adjusted to suit individual patient requirements and characteristics. Use in Children - Dose requirements for young children have not been extensively evaluated. Antacids should not be given to young children (up to 6 years of age) unless prescribed by a physician. Ask a physician before use if you are pregnant or breastfeeding. CONTRAINDICATIONS: Gelusil tablets/liquid should not be used in patients with known sensitivity to any of the ingredients. WARNING AND PRECAUTIONS: Patients over 50 who are experiencing heartburn for the -rst time, and patients who have noticed unintentional weight loss should consult a physician before using the product. Patients should stop use and consult a physician if symptoms persist or worsen, new symptoms develop or if they experience dysphagia, odynophagia, severe vomiting, melaena, choking or chest pain. Patients with renal impairment should consult a physician before using the product. Both magnesium and aluminum are principally eliminated from the kidney, and the risk of developing hypermagnesaemia / aluminum toxicity is increased with impaired renal function. Patients with pre-existing hypermagnesaemia should consult a physician before using the product. Magnesium is systemically absorbed following use of oral magnesium-containing antacids, which could result in an increase in already raised magnesium levels. Gastrointestinal uptake of aluminum is higher in children than in adults and therefore the use of the medicinal product is not recommended in children below 12 years of age. DRUG INTERACTIONS: Antacids have potentially important interactions with Beta-blocking agents, Cimetidine, Chloroquine, Digoxin, NSAIDs, Phenytoin, Tetracyclines, Iron preparations, Fluoroquinolones and Quinidine. Absorption of captopril, dasatinib, itraconazole, rosuvastatin, some tetracyclines including doxycycline, some quinolone antibiotics including ciprooxacin, levooxacin, noroxacin, and ooxacin, may be impaired in the presence of aluminum hydroxide. In general, patients should be advised not to take any other oral medication within 1 to 2 hours of consuming antacids. Patients should consult a physician before using this product together with Raltegravir, Dolutegravir, and Elvitegravir. OVERDOSE: There are no reports of overdosage with Gelusil. Potential

effects, based on the pharmacology of ingredients, include major electrolyte imbalances such as elevated serum magnesium and aluminium levels, hypophosphatemia, metabolic alkalosis, hyperosmolarity and dehydration. In the event of overdosage, symptomatic treatment, with supportive measures and gastric lavage, if necessary, is recommended. ADVERSE REACTION: Gelusil is generally well tolerated. Hydroxides of magnesium and aluminium are minimally absorbed and there is a low risk of systemic side-effects or alkalosis (except in patients with renal failure where hypermagnesemia or increased aluminium levels may occur). PHARMACEUTICAL PRECAUTIONS: Shelf life - 24 months from the date of manufacture. Storage - Tablets: Store in a dry place away from sunlight. Liquid: Store away from sunlight. Shake well before use. Keep bottle tightly closed and avoid freezing. REFERENCE: Version LPDGEL092021 Dated September 2021. DATE OF THIS DOCUMENT: January 25, 2022. Gelusil® Trademark of Warner-Lambert Company LLC, USA. Licensed User. Pfizer Limited, India.