PACKAGE INSERT FOR GELACID SUSPENSION

SCHEDULING STATUS:

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PROPRIETARY NAME (AND DOSAGE FORM):

GELACID (Suspension)

COMPOSITION:

Each 10 ml contains:	Sodium bicarbonate	267 mg
	Sodium alginate	500 mg
	Calcium carbonate	160 mg
Preservatives:	Methyl hydroxybenzoate	0,4 % *m/v*
	Propyl hydroxybenzoate	0,06 % *m/v*
Total sodium content:	6,052 mmol/10 mℓ	

Inactive ingredients include methyl hydroxybenzoate, peppermint flavour, propyl hydroxybenzoate, sodium carboxymethyl cellulose

Contains sweetener: Sodium saccharin 15 mg

PHARMACOLOGICAL CLASSIFICATION:

A 11.10 Medicines acting on gastrointestinal tract: (special combinations).

PHARMACOLOGICAL ACTION:

GELACID protects the mucosa of the gastrointestinal tract and mechanically inhibits reflux by forming a viscous layer on the surface of the gastric contents

INDICATIONS:

GELACID is indicated for gastric reflux, mild to moderate reflux oesophagitis, heartburn, heartburn of pregnancy (see **"PREGNANCY AND LACTATION"**) and hiatus hernia in adults and children over 6 years.

CONTRAINDICATIONS:

- Hypersensitivity to any of the ingredients in **GELACID**.
- **GELACID** should not be administered to patients with metabolic or respiratory alkalosis, hypercalcaemia and hypochlorhydria.

WARNINGS AND SPECIAL PRECAUTIONS:

Do not use the maximum dosage of **GELACID** for more than 2 weeks, except under the advise and supervision of a doctor. Do not use this product if you are on a sodium restricted diet, or suffering from hypertension

or heart failure, except under the supervision of a doctor. GELACID should be administered with caution to patients with congestive cardiac failure, oedema, renal impairment, cirrhosis of the liver and to patients receiving corticosteroids (see “INTERACTIONS”). GELACID can cause stomach cramps and flatulence.

Hypercalcaemia and alkalosis can occur following high doses of calcium

carbonate.

Large doses of GELACID may interfere with the absorption of some medicines (see “INTERACTIONS”).

INTERACTIONS:

Due to the ability of the antacids in GELACID to change gastric or urinary pH and to adsorp or form complexes with other medicines, the rate and/or extent of absorption of other medicines may be increased or reduced when such medicines are used concurrently with antacids (see “WARNINGS AND SPECIAL PRECAUTIONS”). In general, patients should be advised not to take any other oral medicines within 1 to 2 hours of antacids. Medicines of which the absorption may be decreased include, but are not limited to, anticholinergics, H2-receptor antagonists, oral iron preparations, ketoconazole, tetracyclines, and phenytoin. GELACID should be administered with caution to patients receiving corticosteroids (see “WARNINGS AND SPECIAL PRECAUTIONS”).

Concurrent use of thiazide diuretics with large doses of calcium carbonate may result in hypercalcaemia.

Concurrent and prolonged use of milk and milk products with calcium carbonate or sodium bicarbonate may result in the milk-alkali syndrome.

Potential interactions due to urinary alkalinisation may occur with amphetamines, quinidine, ephedrine, fluoroquinolone antibiotics, mexiletine, and salicylates.

PREGNANCY AND LACTATION:

GELACID may be used during pregnancy, but under supervision of a doctor. (see “WARNINGS AND SPECIAL PRECAUTIONS”)

DOSAGE AND DIRECTIONS FOR USE:

Adults and children over 12 years:

Take two to four medicine measures (10 – 20 ml) after meals and at bedtime. Eighty (80) ml (16 medicine measures) should be the maximum dosage per day (24 hour period).

Children between 6 and 12 years:

Take two medicine measures (10 ml) after meals and at bedtime.

Forty (40) ml (8 medicine measures) should be the maximum dosage per day (24 hour period).

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-Effects:

Calcium carbonate:

Metabolism and nutrition disorders:

Frequency unknown:	Metabolic alkalosis with large doses or in patients with renal insufficiency.

Gastrointestinal disorders:

Frequent:	Chalky taste.
Less frequent:	Constipation.
Frequency unknown:	Faecal impaction (large doses).

Renal and urinary disorders:

Frequency unknown:	Hypercalcaemia associated with milk-alkali syndrome may occur with large doses of calcium carbonate and/or in patients with chronic renal failure. Overuse or prolonged use of calcium carbonate may give rise to renal calculi.

General disorders and administrative site conditions:

Frequency unknown:	Swelling of the feet or lower legs.

Sodium bicarbonate:

Metabolism and nutrition disorders:

Frequency unknown:	Excessive administration of sodium bicarbonate may lead to hyperkalaemia and metabolic alkalosis, especially in patients with impaired renal function. Symptoms may include muscle weakness, shortness of breath,

	tiredness, mood changes and irregular heartbeat. With long-term or prolonged use, antacids containing sodium bicarbonate may cause hypercalcaemia associated with milk-alkali syndrome

Cardiac disorders:

Frequency unknown:	Congestive heart failure may occur due to excessive sodium absorption.

Gastrointestinal disorders:

Less frequent:	Increased thirst, stomach cramps.
Frequency unknown:	Belching and flatulence.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

A feeling of abdominal distension may occur with very large doses of **GELACID**.

Treatment is symptomatic and supportive.

IDENTIFICATION:

Opaque off-white to cream suspension with peppermint flavour.

PRESENTATION:

Amber coloured glass or plastic bottles containing 100 ml or 200 ml suspension.

STORAGE INSTRUCTIONS:

Store at or below 25 °C in a dry place.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

33/11.10/0046

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD.

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