SCHEDULING STATUS: S0

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	

PHARMACOLOGICAL CLASSIFICATION:

A 11.10 Drugs 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.

CONTRA-INDICATIONS:

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

WARNINGS:

Do not use the maximum dosage of this product for more than 2 weeks, except under the advice 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.

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 **"SIDE-EFFECTS 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 **"SIDE-EFFECTS 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"**).

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 medicines measures) should be the maximum dosage per day (24 hour period).

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects:

Calcium carbonate:

Metabolism and nutrition disorders:

The following side-effects have been reported and frequencies are unknown: Metabolic alkalosis with large doses or in patients with renal insufficiency.

Gastrointestinal system disorders:

Frequent: Chalky taste.
Less frequent: Constipation.
The following side-effects have been reported and frequencies are unknown: Faecal impaction (large doses).

Renal and urinary system disorders:

The following side-effects have been reported and frequencies are 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:

The following side-effects have been reported and frequencies are unknown: Swelling of the feet or lower legs.

Sodium bicarbonate:

Metabolism and nutrition disorders:

The following side-effects have been reported and frequencies are 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.

Cardiovascular system disorders:

The following side-effects have been reported and frequencies are unknown: Congestive heart failure may occur due to excessive sodium absorption.

Gastrointestinal system disorders:

Less frequent: Increased thirst, stomach cramps.
The following side-effects have been reported and frequencies are unknown: Belching and flatulence have been reported.

Special Precautions:

GELACID should be administered with caution to patients with congestive cardiac failure, oedema, renal impairment, cirrhosis of the liver, hypertension 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"**).

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.
Building 9, Parc du Cap
Mispel Street, Bellville, 7530, RSA

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

July 2009

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SKEDULERINGSTATUS: S0

EIENDOMSNAAM (EN DOSEERVORM):

GELACID (Suspensie)

SAMESTELLING:

Elke 10 ml bevat:	Natriumbikarbonaat	267 mg
	Natriumalginaat	500 mg
	Kalsiumkarbonaat	160 mg
Preserveermiddels:	Metielhidroksibensoaat	0,4 % m/v
	Propielhidroksibensoaat	0,06 % m/v
Totale natriuminhoud:	6,052 mmol/10 ml	

FARMAKOLOGIESE KLASSIFIKASIE:

A 11.10 Middels wat op die gastro-intestinale kanaal inwerk (spesiale kombinasies).

FARMAKOLOGIESE WERKING:

GELACID beskerm die slymvliese van die gastro-intestinale kanaal en veroorsaak 'n meganiese inhibisie van refluks deur 'n viskeuse laag op die maaginhoud te vorm.

INDIKASIES:

GELACID is aangedui vir gastriese refluks, ligte tot matige refluksesofagitis, sooibrand, swangerskapsooibrand (sien **"SWANGERSKAP EN LAKTASIE"**) en hiatusbreuk in volwassenes en kinders ouer as 6 jaar.

KONTRA-INDIKASIES:

- Hipersensitiwiteit vir enige van die bestanddele in **GELACID**.
- **GELACID** moenie aan pasiënte met metaboliese of respiratoriese alkalose, hiperkalsemie en hipochloorhidrie toegedien word nie.

WAARSKUWINGS:

Moenie die maksimum dosis van hierdie produk vir langer as twee weke gebruik nie, behalwe op advies en onder toesig van 'n geneesheer.

Moenie hierdie produk gebruik indien u op 'n lae sout (beperkte natrium) dieet is, of indien u aan hipertensie of hartversaking ly nie, behalwe onder toesig van 'n geneesheer.

INTERAKSIES:

Vanweë die vermoë van die teensure in **GELACID** om die gastriese of urinêre pH te verander en om komplekse met ander geneesmiddels te vorm of dit te adsorbeer, mag teensure die tempo en/of omvang van absorpsie van ander middels vermeerder of verminder wanneer sodanige middels saam met teensure toegedien word (sien **"NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS"**). Pasiënte behoort oor die algemeen geadviseer te word om nie enige ander orale medikasie binne 1 tot 2 ure na die inname van teensure te gebruik nie. Middels waarvan die absorpsie mag verminder, sluit onder andere anticholinergiese middels, H2-reseptor antagoniste, orale ysterpreparate, ketokonasool, tetrasikliene en fenitoïen in.

GELACID moet met sorg toegedien word aan pasiënte wie kortikosteroïede (sien **"NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS "**) ontvang.

Gesamentlike gebruik van tiasieddiuretika met groot dosisse kalsiumkarbonaat mag tot hiperkalsemie lei.

Gelyktydige en verlengde gebruik van melk en melkprodukte saam met kalsiumkarbonaat of natriumbikarbonaat mag tot melk-alkali sindroom lei.

Potensiële interaksies vanweë urinêre alkalinisering mag met amfetamiene, kinidien, efedrien, fluorokwinoloon antibiotika, meksiletien en salisilate voorkom.

SWANGERSKAP EN LAKTASIE:

GELACID mag tydens swangerskap onder die toesig van 'n geneesheer gebruik word (sien **"WAARSKUWINGS"**).

DOSIS EN GEBRUIKSAANWYSINGS:

Volwassenes en kinders ouer as 12 jaar:

Neem twee tot vier medisynemate (10 – 20 ml) na maaltye en met slaaptyd.

Tagtig (80) ml (16 medisynemate) behoort die maksimum dosis per dag (24 uur periode) te wees.

Kinders tussan 6 en 12 jaar:

Neem twee medisynemate (10 ml) na maaltye en met slaaptyd.

Veertig (40) ml (8 medisynemate) behoort die maksimum dosis per dag (24 uur periode) te wees.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Newe-effekte:

Kalsiumkarbonaat:

Metabolisme en voedingsafwykings:

Die volgende newe-effekte is gemeld en die frekwensie daarvan is onbekend: Metaboliese alkalose met groot doserings of in pasiënte met renale ontoereikendheid.

Gastro-intestinale sisteem afwykings:

Dikwels: Kalkagtige smaak.

Minder dikwels: Hardlywigheid.

Die volgende newe-effekte is gemeld en die frekwensie daarvan is onbekend: Fekale impaksie (met groot dosisse).

Renale en urinêre sisteem afwykings:

Die volgende newe-effekte is gemeld en die frekwensie daarvan is onbekend: Hiperkalsemie geassosieer met melk-alkali sindroom mag voorkom met groot dosisse kalsiumkarbonaat en/of in pasiënte met chroniese nierversaking.

Oormatige of verlengde gebruik van kalsiumkarbonaat mag tot die ontwikkeling van nierstene aanleiding gee.

Algemene afwykings:

Die volgende newe-effekte is gemeld en die frekwensie daarvan is onbekend: Swelling van die voete of onderbene.

Natriumbikarbonaat:

Metabolisme en voedingsafwykings:

Die volgende newe-effekte is gemeld en die frekwensie daarvan is onbekend: Oormatige toediening van natriumbikarbonaat mag tot hiperkalemie en metaboliese alkalose aanleiding gee, veral in pasiënte met ingekorte nierfunksie. Simptome mag spierswakheid, kortasemheid, gemoedsveranderinge, moegheid en onreëlmatige hartklop insluit.

Met langtermyn of verlengde gebruik mag teensuurmiddels wat natriumbikarbonaat bevat hiperkalsemie geassosieer met melk-alkali sindroom veroorsaak.

Kardiovaskulêre sisteem afwykings:

Die volgende newe-effekte is gemeld en die frekwensie daarvan is onbekend: Kongestiewe hartversaking mag vanweë oormatige natriumabsorpsie voorkom.

Gastro-intestinale sisteem afwykings:

Minder dikwels: Vermeerderde dors, maagkrampe.

Die volgende newe-effekte is gemeld en die frekwensie daarvan is onbekend: Winde opbreek en winderigheid is gemeld.

Spesiale Voorsorgmaatreëls:

GELACID moet met sorg aan pasiënte met kongestiewe hartversaking, edeem, ingekorte nierfunksie, sirrose van die lewer en hipertensie asook aan pasiënte wie kortikosteroïede (sien **"INTERAKSIES"**) ontvang, toegedien word.

GELACID mag maagkrampe en winderigheid veroorsaak.

Hiperkalsemie en alkalose mag voorkom na die inname van hoë dosisse **GELACID**.

Hoë dosisse **GELACID** mag inmeng met die absorpsie van sommige geneesmiddels (sien **"INTERAKSIES"**).

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

'n Gevoel van buikopsetting mag na groot dosisse **GELACID** voorkom. Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

Ondeursigtige naaswit tot room suspensie met pepermentgeur.

AANBIEDING:

Bruingekleurde glas- of plastiekbottels gevul met 100 ml of 200 ml suspensie.

BERGINGSINSTRUKSIES:

Berg teen of benede 25 °C in 'n droë plek.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

33/11.10/0046

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:

CIPLA MEDPRO (EDMS) BPK.
Gebou 9, Parc du Cap
Mispelstraat, Bellville, 7530, RSA

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:

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