# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Remegel 800 mg Chewable Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 800mg Calcium Carbonate.

Excipients with known effect: each tablet contains 99.71mg sorbitol (E420), 1.47g sucrose and 992.5mg glucose.
For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Chewable tablet.

Light green, soft, chewable squares with bevelled edges and rounded corners.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Remegel tablets are indicated for the relief of stomach upsets due to hyperacidity and heartburn.

### 4.2 Posology and method of administration

Route of administration: Oral. Tablets to be chewed and swallowed.

**Adults and children 12 years and over:**
One or two tablets of Remegel to be chewed as a single dose, when symptoms occur. Repeat as necessary. Maximum dose: 12 tablets in 24 hours.

**Children under 12 years of age:**
Not recommended.

**The elderly:**
As for adults, see above.

**Hepatic dysfunction:**
There is no specific information relating to the use of Remegel in hepatic impairment. Normal adult dosage is appropriate.

**Renal dysfunction:**
Remegel should be used with caution in subjects with mild to moderate renal impairment (see section 4.4). Current use of calcium carbonate as a phosphate binder should be taken into account to prevent hypercalcaemia. Use in severe renal impairment is contraindicated (see sections 4.3).

### 4.3 Contraindications

Hypersensitivity to the active ingredient or any of the excipients, refer to section 6.1
Hypercalcaemia
Nephrocalcinosis
Patients with renal calculi, or with history of renal calculi
Severe renal function impairment (creatinine clearance below 30ml/min)
Hypophosphataemia

### 4.4 Special warnings and precautions for use

Use with caution in patients with renal dysfunction (see Posology and Method of Administration).

Long term uses at high doses can result in undesirable effects such as hypercalcaemia and milk alkali syndrome, especially in patients with renal insufficiency. Prolonged use possibly enhances the risk for development of renal calculi.

Calcium carbonate should be used with caution in patients with hypercalciuria.

This product contains sucrose and glucose syrup and as such, care is required in patients with diabetes mellitus.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

The elderly should take care to observe warnings and contra-indications, due to increased susceptibility to adverse drug reactions, by means of age-related changes and polypharmacy.

Prolonged use should be avoided. Do not exceed the stated dose and if symptoms persist, despite 7 days of continuous therapy, the clinical situation should be reviewed by a medical professional. Diagnostic measures are recommended in order to rule out a more serious disease.

Keep out of the sight and reach of children.

**4.5 Interaction with other medicinal products and other forms of interactions**

Changes in gastric acidity, such as that caused by the ingestion of antacids, can affect the rate and degree to which some concurrently administered medicines are absorbed. It is recommended that antacids are not taken simultaneously with other medications, but spaced at least 2 hours apart.

In common with other antacids, calcium carbonate may form complexes with certain drugs e.g., antibiotics (such as tetracyclines and quinolones) and cardiac glycosides (digoxin), H2-antihistaminics, fluoroquinolone, iron containing drugs, ketoconazole, neuroleptics, thyroxine, penicillamine, beta-blockers (atenolol, metoprolol, propanolol), glucocorticoid, chloroquine, estramustine and diphosphonates leading to their reduced absorption. This should be taken into account when concomitant administration is considered.

Thiazide diuretics reduce the urinary excretion of calcium and increase the serum calcium.

**4.6 Fertility, pregnancy and lactation**

Pregnancy
No increased risk of congenital defects has been observed after the use of calcium carbonate during pregnancy. Calcium carbonate can used during pregnancy if taken as instructed but prolonged intake of high doses should be avoided.

Breast-feeding
There is no information relating to the excretion of Remegel in breast milk. Calcium carbonate can be used during lactation if taken as instructed.

Fertility
No known effect.

**4.7 Effects on ability to drive and use machines**

None known.

**4.8 Undesirable effects**

Adverse events which have been associated with calcium carbonate are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common (≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000 and <1/100); 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 | Not Known | Hypersensitivity, anaphylactic reaction[1] |
| Metabolism and Nutrition disorders | Not Known | Hypercalcaemia, alkalosis |
| Gastrointestinal Disorders | Not Known | Eructation, constipation, nausea, vomiting, abdominal discomfort, diahorrea |

[1] Symptoms may include rash, urticarial, angioedema

**Reporting of Suspected Adverse Reactions**
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Pharmacovigilance Section, Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517;
Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

**4.9 Overdose**

Excessive ingestion of calcium carbonate, especially in patients with impaired renal function can lead to hypercalcaemia, renal insufficiency and alkalosis, characterised by gastro-intestinal symptoms (pain, nausea, vomiting, constipation) and muscular weakness. In these cases, the intake of the product should be stopped and adequate isotonic fluid intake encouraged. In severe cases of overdosage, milk-alkali syndrome may occur.

Haemodialysis and other therapeutic measures such as saline diuresis have been used to successfully treat excessive ingestion of calcium carbonate antacid.

**5 PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

Pharmacotherapeutic Classification: Antacids
ATC Code: Calcium carbonate: A02AC01

Calcium carbonate is a potent antacid, neutralising gastric acid when taken by the oral route.

**5.2 Pharmacokinetic properties**

**Absorption:**
Calcium carbonate is converted to calcium chloride by gastric acid (hydrochloric acid) in the stomach, with the resulting formation of carbon dioxide and water. Some of the calcium is absorbed from the intestines but the majority is reconverted into insoluble calcium salts such as carbonate and stearate, which is excreted in the faeces.

**Distribution, Metabolism and Elimination:**
Once absorbed from the stomach, physiological concentrations of calcium are tightly controlled, principally through the effects of parathyroid hormone, vitamin D and its metabolites and calcitonin. These control mechanisms are well documented in standard texts.

**5.3 Preclinical safety data**

Pre-clinical safety data does not add anything of further significance to the prescriber.

**6 PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Sucrose
Glucose Liquid
Purified Water

Hyfoama DS (hydrolysed milk protein)
Gelatin
Maize Starch
Sorbitol (E420)
Glycerol (E422)
Titanium Dioxide (E171)
Patent blue V (E131)
Quinoline yellow (E104)
Paramount C (hydrogenated vegetable fat)
Amerfond Fondant Sugar
Peppermint oil
Levomenthol
Butylhydroxyanisole (E320)
Talc

**6.2 Incompatibilities**

Not applicable.

**6.3 Shelf life**

2 years.

**6.4 Special precautions for storage**

Do not store above 25$^{o}$C. Store in original package in order to protect from moisture.

**6.5 Nature and contents of container**

Each tablet in stickpacks is wrapped in printed waxed paper and overwrapped in hermetically sealed aluminium foil stickpack.
5 piece stickpack
8 piece stickpack
8 piece stickpack, 3 stickpacks per carton
8 piece stickpack, 5 stickpacks per carton
8 piece stickpack, 6 stickpacks per carton
Not all pack sizes may be marketed.

**6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

**7 MARKETING AUTHORISATION HOLDER**

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

**8 MARKETING AUTHORISATION NUMBER**

PA0979/077/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 13$^{th}$ October 1992
Date of last renewal: 13$^{th}$ October 2007

**10 DATE OF REVISION OF THE TEXT**

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