Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rennie Orange 500mg Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Calcium Carbonate 500 mg (200mg elemental calcium).

Excipients with known effect:
Each chewable tablet also contains ponceau 4R (E124) and 887.5 mg sucrose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet
A square orange chewable tablet with rounded corners, bevelled edges and concave faces.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of stomach upset due to hyperacidity and heartburn, e.g. indigestion, hyperacidity, flatulence, dyspepsia, biliousness, and acid indigestion.

4.2 Posology and method of administration

Tablets to be taken orally, sucked or chewed, according to the following dosage schedules:

Adults:
One or two tablets to be sucked or chewed as required, to a maximum of eleven tablets a day and should not be taken continuously for longer than 2 weeks.

Elderly
No special dosage regimen is required, but care should be taken to observe the contraindications and warnings.

Children
Not recommended for children under 12 years of age.

4.3 Contraindications

Rennie Orange should not be administered in the following cases:

- Hypersensitivity to any of the ingredients of the product
- Hypercalcaemia, hypercalciuria and/or conditions resulting in hypercalcaemia e.g sarcoidosis

- Nephrolithiasis due to calculi containing calcium deposits
- Severe renal insufficiency
- Hypophosphatemia

4.4 Special warnings and precautions for use

Rennie Orange

Prolonged use should be avoided. Do not exceed the stated dose and if symptoms persist after seven days, further medical advice should be sought.

Caution should generally be exercised in the case of patients with impaired renal function. If Rennie Orange is to be used in these patients, plasma calcium and phosphate levels should be regularly monitored.

As with other antacids, Rennie Orange tablets may mask a malignancy in the stomach. Long term use at high doses can result in undesirable effects such as hypercalcaemia and milk alkali syndrome, especially in patients with renal insufficiency. The product should not be taken with large amounts of milk or dairy products.

Prolonged use increases the risk for the development of kidney stones.

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

Rennie Orange contains Ponceau 4R (E124) which may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Changes in gastric acidity, e.g. during treatment with antacids, may impair the rate and degree of absorption of other drugs, if taken concomitantly.

- It has been shown that antacids containing calcium may form complexes with certain substances, e.g. antibiotics (tetracyclines, quinolones), cardiac glycosides, e.g. digoxin, bisphosphonates, dolutegravir, levothyroxine and eltrombopag resulting in decreased absorption. This should be borne in mind when concomitant administration is considered.

- Calcium salts can also impede the absorption of phosphates, fluorides, and iron containing products.

- Thiazide diuretics reduce the urinary excretion of calcium. Due to an increased risk of hypercalcaemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics.Therefore it is preferable to administer the antacid separately from other drugs, allowing a 1-2 hours interval.

4.6 Fertility, pregnancy and lactation

Pregnancy

- Animal studies do not indicate reproductive toxicity (see section 5.3).
- No increased risk of congenital defects are anticipated, neither has been observed after the use of calcium carbonate during pregnancy. In case of high or prolonged doses or renal insufficiency, the risk for hypercalcaemia and/or hypermagnesaemia can not be completely excluded.
- Rennie Orange tablets can be used during pregnancy if taken as instructed.
- The maximum recommended daily dose should not be exceeded and should not be taken for more than 2 weeks (see section 4.2).
- In order to prevent calcium overload, pregnant women should avoid concomitant excessive intake of milk and dairy products.

Breastfeeding

Calcium carbonate is excreted in human milk, but at therapeutic doses of Rennie Orange no effects on the breastfed newborns/infants are anticipated.

Fertility

There is no known evidence suggestive that at recommended dose Rennie Orange have adverse effects on human fertility.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

The listed adverse drug reactions are based on spontaneous reports, thus an organisation according to CIOMS III categories of frequency is not possible.

Immune System Disorders
Hypersensitivity reactions have very rarely been reported. Clinical symptoms may include rash, urticaria, pruritus, angioedema, dyspnea and anaphylaxis.

Metabolism and Nutrition Disorders
Especially in patients with impaired renal function, prolonged use of high doses can result in hypercalcaemia and alkalosis.

Gastrointestinal Disorders
Nausea, vomiting, stomach discomfort, constipation and diarrhea may occur.

Musculoskeletal and Connective Tissue Disorders
Muscular weakness may occur.

Undesirable effects only occurring in the context of milk-alkali syndrome (see section 4.9):
Gastrointestinal Disorders
Ageusia may occur in the context of milk-alkali syndrome.

General Disorders and Administration Site Conditions
Calcinosis and asthenia may occur in the context of milk-alkali syndrome.

Nervous System Disorders
Headache may occur in the context of milk-alkali syndrome.

Renal and Urinary Disorders
Azotemia may occur in the context of milk-alkali syndrome.

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 HPRA Pharmacovigilance Website: www.hpra.ie.

4.9 Overdose

Especially in patients with impaired renal function, prolonged use of high doses of calcium carbonate can result in renal insufficiency, hypercalcaemia and alkalosis which may give rise to gastrointestinal symptoms (nausea, vomiting, constipation) and muscular weakness. In these cases, the intake of the product should be stopped and adequate fluid intake encouraged. In severe cases of overdosage (e.g. milk-alkali syndrome), a health care professional must be consulted because other measures of rehydration (e.g. infusions) might be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antacid; ATC code: A02A

ATC-Code: Calcium carbonate A02AC01

Rennie Orange contains calcium carbonate as an antacid. The mode of action of calcium carbonate is local, based on the neutralisation of gastric acid, and is not dependent on systemic absorption. Calcium carbonate has a rapid, long-lasting and powerful neutralising action.

5.2 Pharmacokinetic properties

In the stomach, calcium carbonate reacts with the acid in the gastric juice, forming water and soluble mineral salts.

$CaCO_3 + 2\ HCl \rightarrow CaCl_2 + H_2O + CO_2$

Calcium can be absorbed from these soluble salts. However, the degree of absorption depends on the subject and the dose. Less than 10% of calcium is absorbed.

The small quantities of calcium absorbed are usually excreted rapidly via the kidneys in healthy individuals. In the case of impaired renal function, plasma concentration of calcium may be increased.

Due to the effects of various digestive juices outside the stomach, the soluble salts are converted to insoluble salts in the intestinal canal and then excreted with the faeces.

5.3 Preclinical safety data

No additional data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Potato starch
Pregelatinised maize starch
Magnesium stearate
Talc
Citric acid
Orange flavour
Quinoline yellow (E104)
Ponceau 4R (E124)
Saccharin.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Tablets are packed in clear styrolex bottles with polypropylene lids, containing 30, 70, 100, or 150 tablets.

Alternatively, 8 tablets are roll wrapped in laminated foil.
Alternatively, tablets are packed in aluminium foil/pvc blister strips with 4, 8 or 12 tablets per strip. 1, 2, 3, 4, 6, 8, 10 or 12 strips are placed in a cardboard carton. (8, 12, 24, 32, 48, 60, 64, 72, 80, 96 or 120 tablets per carton), which may contain one or more cut-out "windows". Alternatively one strip of 8 tablets is presented in a cardboard sample wallet, which may contain one or more cut-out "windows".

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

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8 MARKETING AUTHORISATION NUMBER

PA1410/054/001

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Date of last renewal: 26 November 2005

10 DATE OF REVISION OF THE TEXT

November 2022