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PROFESSIONAL INFORMATION

Complementary Medicine Health Supplement

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

Rennie Salts effervescent powder 60 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Rennie salts is a health supplement with calcium, in the form of effervescent granules with a lemon flavour.

Each 3,1 g sachet contains following active ingredients:

Ingredient Name	Quantity
Calcium (Calcium citrate)	60 mg

Sugar free.
Contains sweetener: Sucralose 2.4 mg per sachet.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Effervescent powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Rennie salts is a health supplement which helps relieve symptoms of indigestion and abdominal discomfort/pain.

4.2 Posology and method of administration

Posology

For oral use.
The recommended intake for adults and adolescents (above 15 years of age) is two (1) sachet per day

4.3 Contraindications

- Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1.
- Hypercalcaemia
- This product is not intended for use during pregnancy and lactation.

4.4 Special warnings and precautions for use

- Do not exceed the recommended daily intake.
- If the troublesome digestion persists after 7-10 days of treatment, please seek medical advice.
- If you have any medical condition, take medication or are on a controlled sodium diet, please seek medical advice before taking the product.
- Long term use without medical advice is not recommended due to the potential risk of masking severe diseases.

- Sensitive patients, who may experience an increased risk of adverse effects with intake of the product, are limited to people with hypersensitivity to any component in the product.
- The sodium amount in Rennie Salts should be taken into consideration, especially for people on a controlled sodium diet.
- People with existing alkalosis and electrolyte imbalance or other medical conditions should consult their healthcare professional before taking the product.
- The risk of metabolic alkalosis or fluid and sodium retention should still be considered when taken during pregnancy or lactation. Medical advice is needed for these populations groups before taking the product.

Paediatric population

- This product is not indicated for children below 15 years.

4.5 Interaction with other medicines and other forms of interaction

Potential interactions with citric acid are very rare. Many medications can interact with calcium. Additionally, since sodium bicarbonate might alter gastric pH value, the absorption of other medications could be impacted theoretically. It is advisable to consult HCPs, if this product is taken concomitantly with other medications.

Drug interactions

Active Ingredient	Drug	Description
Calcium	Thiazide diuretics	Thiazide diuretics reduce the urinary excretion of calcium. Due to an increased risk of hypercalcemia, serum calcium should be regularly monitored during concomitant of thiazide diuretics
	Vitamin D	Vitamin D increases the gastrointestinal absorption of calcium
	Bisphosphonates	Polyvalent cations, such as calcium form complexes with certain substances resulting in decreased absorption of both substances. Doses should be separated by at least 3 hours
	Fluoride	
	Tetracyclines	
	Fluoroquinolones	

4.6 Fertility, pregnancy and lactation

Pregnancy and Breastfeeding

If pregnant or breast-feeding, please ask your health care provider before using the product.

4.7 Effects on ability to drive and use machines

The product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Rennie Salts effervescent powder may have undesirable effects.

Immune system disorders

Frequency unknown: Hypersensitivity reaction, anaphylactic reaction, anaphylactic shock.

If an allergic reaction occurs, treatment must be stopped and a health care professional consulted affecting skin, respiratory tract, gastrointestinal tract, and cardiovascular system, including symptoms such as rash, urticaria, allergic

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
Alternatively you can report the side effects directly to Bayer Pharmacovigilance Department by sending and, email to zapv@bayer.com or via the Bayer website (www.bayer.co.za).

4.9 Overdose
General manifestations of overdose may include hypercalcaemia. This complication is usually associated with parental use, but can occur after oral dosage, usually in patients with renal failure or who are taking vitamin D. symptoms of hypercalcaemia include anorexia, nausea, vomiting, constipation, abdominal pain and muscle weakness.. If such symptoms occur, the product should be stopped, and a health care professional consulted.
Specific clinical signs and symptoms, laboratory findings, and consequences of overdose are highly diverse, dependent on an individual's susceptibility, and surrounding circumstances.
If overdose with the product is suspected, intake should be stopped, and a health care professional consulted for treatment of clinical manifestations.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacological classification: category D 34.7 (Minerals).
ATC code: **A12AA**.
Rennie Salts effervescent powder is a mineral preparation.

5.2 Pharmacokinetic properties
There is no specific study with this product, but the pharmacokinetic properties of the individual components have been extensively documented.
Calcium is absorbed mainly from the small intestine by active transport and passive diffusion. About one-third of ingested calcium is absorbed although this can vary depending upon dietary factors and the state of the small intestine; also, absorption is increased in calcium deficiency and during periods of high physiological requirement such as during childhood or pregnancy and lactation. 1,25 Dihydroxycholecalciferol, a metabolite of vitamin D, enhances the active phase of absorption.
Excess calcium is mainly excreted renally. Unabsorbed calcium is eliminated in the faeces, together with that secreted in the bile and pancreatic juice. Minor amounts are lost in the sweat, skin, hair and nails. Calcium crosses the placenta and is distributed into breastmilk.

5.3 Preclinical safety data
There is no specific study with this product, but the preclinical safety of the individual components has been extensively documented.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Citric acid;
Sodium Hydrogen carbonate
Sorbitol;
Lemon Juice;
Sucralose[1]

[1] sweetener

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months

6.4 Special precautions for storage
Store at or below 25°C.
Store in a cool dry place.

6.5 Nature and contents of container
PAP-ALU-PE/E sachets containing 3,1 g of effervescent powder. 20 Sachets are packed in secondary packaging (folding carton) with a leaflet.

6.6 Special precautions for disposal
No special requirements

7. Holder of Certificate of Registration
Bayer (Pty) Ltd.
Co Reg. no.: 1968/011192/07
1st Floor, Collaboration Hub, Waterfall Circle, 9 Country Estate Drive
Waterfall City, Midrand, Johannesburg,2090, South Africa
Tel: +27 11 921 5000

8. Registration number(s)
To be confirmed upon registration.

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION
To be confirmed upon registration.

10. Date of revision of text
To be confirmed upon registration.

11. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION
To be confirmed upon registration