Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Magnesium Verla 5 mmol granules for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 g sachet of granules contains magnesium aspartate dihydrate equivalent to 121.56 mg (5 mmol) of magnesium.

Excipient(s) with known effect:
Sucrose 2.84 g per sachet
Lactose 2.3 mg per sachet

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Granules for oral solution
Yellow-tinged, free-flowing granules for solution with a slight odour and taste of tangerine that reduces during storage.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the correction of magnesium deficiency.

4.2 Posology and method of administration

Adults and children over 10 years of age: The contents of one sachet (5 g) in-water, tea or fruit juice 1-3 times daily.

Children 2 to 10 years: The contents of one sachet (5 g) in water, tea or fruit juice daily.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Use in patients with oliguria, anuria, severe renal insufficiency, dehydration and diathesis for secondary renal calculi.

4.4 Special warnings and precautions for use

The product should be administered with caution in cases of impaired renal function.
Consideration should be given to monitoring electrolytes.
Magnesium Verla contains sucrose, lactose and sodium

1. The sugar content requires caution when used in diabetics.
2. This medicinal product contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
3. This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.
4. This medicinal product contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interactions

To avoid impairment of absorption, magnesium preparations should be taken three to four hours before or after the administration of tetracyclines, iron or sodium fluoride preparations.

4.6 Fertility, pregnancy and lactation

Use of the product during pregnancy and lactation is recommended where a deficiency has been demonstrated.

4.7 Effects on ability to drive and use machines

Magnesium Verla does not normally produce any effects on ability to drive or use machines.

4.8 Undesirable effects

Soft stools or diarrhoea may be observed following administration of Magnesium Verla 5 mmol granules for oral solution. This may result from high dosage oral magnesium therapy. In such cases the daily dosage should be reduced.

Although hypermagnesaemia would not be expected, unless the patient had impaired renal function, the symptoms of hypermagnesaemia include the following: thirst, nausea, vomiting, flushing of the skin, hypotension, drowsiness, confusion, loss of tendon reflexes, muscle weakness, respiratory depression, cardiac arrhythmias, coma and cardiac arrest.

The following frequency data is the basis for the description of adverse reactions: Very common (>1/10), common (>1/100, <1/10), uncommon (>1/1000, <1/100), rare (>1/10000), very rare (<1/10000).

Gastrointestinal disorders
Uncommon: Loose stools or diarrhoea

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

Excessive administration of magnesium may cause diarrhoea. In patients with impaired renal function, hypermagnesaemia may occur. Treatment involves restriction of magnesium intake. In severe cases, administration of intravenous calcium salts will reverse the symptoms of hypermagnesaemia. Dialysis may be necessary in patients with renal impairment and severe hypermagnesaemia.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group
The active ingredient in Magnesium Verla is magnesium-aspartate dihydrate, which provides magnesium as a mineral supplement.

Mechanism of Action
Magnesium is involved in activation of more than 300 enzymes, especially those which are ATP dependent.
Magnesium also acts as a physiological calcium antagonist, and as such regulates the contractility of the heart and stabilises cardiac rhythm.

5.2 Pharmacokinetic properties

(a) **General Characteristics of the Active Substance(s)**

Magnesium is 25-30% protein bound, and excreted mainly in the urine. Over 90% of magnesium filtered by the kidney is reabsorbed.

(b) **Characteristics in Patients**
Magnesium should be administered with caution to patients with impaired renal function.

5.3 Preclinical safety data

Not relevant.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Anhydrous citric acid
Saccharin sodium
Mandarin flavour (contains lactose)
Colloidal anhydrous silica

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Sachet of surlyn compound foil which comprises kraft paper coated with polyethylene glued on the smooth side of the aluminium foil, the outer side of the foil is covered with an overlacquer of cellulosenitrate. Each sachet containing 5g is supplied in cartons of 20 and 50 sachets.

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

Rowa Pharmaceuticals Limited
Newtown
Bantry
Co. Cork
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0074/062/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 February 1997

Date of last renewal: 25 February 2007

10 DATE OF REVISION OF THE TEXT