SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Magnesium Aspartate Kora Healthcare 10 mmol Powder for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 sachet contains 3.245 g magnesium aspartate dihydrate (equivalent to 243 mg or 10 mmol magnesium)

Excipient(s) with known effect:
One sachet contains 19 mmol (435 mg) sodium and 2.6 g of sorbitol.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution

White powder

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Magnesium Aspartate Kora Healthcare is indicated for the treatment and prevention of magnesium deficiency in adults and children aged 10 years and above.

4.2 Posology and method of administration

The duration of magnesium treatment required will depend on the clinical circumstances of each patient.

It is recommended that serum magnesium levels should be monitored at regular intervals e.g. every 3-6 months, particularly in children and in patients with renal impairment.

Posology

Adults (>18 years)

1 – 2 sachets daily (243-486 mg magnesium or 10-20 mmol magnesium)

Children and adolescents (10 to 18 years)

1 sachet daily (243 mg magnesium or 10 mmol magnesium)

Renal patients:

Magnesium Aspartate Kora Healthcare is contraindicated in patients with severe renal impairment (see section 4.3).

Method of administration:

For oral use after solution in water.

Magnesium Aspartate Kora Healthcare can be dissolved in 50-200 mL of water.

Stir until the solution in water is cloudy to transparent. In orange juice or tea inactive particles will be visible.

If necessary, Magnesium Aspartate Kora Healthcare in 200ml water can be administered via a gastric, duodenal, and nasal feeding tube. This should be administered immediately following reconstitution or within 24 hours when dissolved in bottled water and stored below 25°C.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Severe renal impairment (glomerular filtration rate < 30 ml/min).
- Disorders of cardiac conduction (eg. AV block, bradycardia).

4.4 Special warnings and precautions for use

In the case of confirmed magnesium deficiency, concomitant hypocalcaemia and hypokalaemia should be suspected and corrected if confirmed since magnesium deficiency is frequently secondary to those conditions.

If an undesirable effect occurs, such as diarrhoea, the therapy should be temporarily interrupted and can be restarted after improvement and /or elimination of the symptoms with a reduced dosage.

The bioavailability of magnesium preparations can vary; therefore, caution should be exercised when switching between magnesium preparations to ensure tolerability and equivalent therapeutic effect.

Excipients:

Sorbitol is a source of fructose. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

This medicinal product contains 435 mg sodium per dose, equivalent to 7 % of the

WHO recommended maximum daily intake for sodium.

The maximum daily dose of this product is equivalent to 14 % of the WHO

recommended maximum daily intake for sodium.

Magnesium Aspartate Kora Healthcare is considered high in sodium. This should be particularly taken into

account for those on a low salt diet.

4.5 Interaction with other medicinal products and other forms of interaction

Caution is advised when taking Magnesium Aspartate Kora Healthcare with the following medicinal products in order to avoid reduced absorption of the active substances due to complex formation:

- ***Cellulose sodium phosphate; edetate disodium****:* concurrent use with magnesium supplements may result in binding of magnesium; patients should be advised not to take magnesium supplements within 1 hour of cellulose sodium phosphate or edetate disodium.
- ***Fluorides and tetracycline****:* if they must be used, the doses must be separated by 2 to 3 hours or more to prevent their admixture in the gut.
- ***Aminoquinolines, quinidine and quinidine derivatives nitrofurantoin, penicillamine, iron, bisphosphonates, eltrombopag, nitroxoline:*** to avoid impairment of absorption, magnesium preparations should be taken 3 to 4 hours before or after the administration of those drugs.

Because of increased magnesium losses, a dose adjustment of magnesium may be necessary when taking the following substances:

- Aminoglycoside antibiotics, cisplatinum and ciclosporin A
- Diuretics (such as thiazide and furosemide),
- EGF-receptor antagonists (such as cetuximab and erlotinib),
- proton pump inhibitors (such as omeprazole and pantoprazole) and
- viral DNA polymerases-inhibiting foscarnet, pentamidine, rapamycin and amphotericin B

4.6 Fertility, pregnancy and lactation

Pregnancy

Magnesium Aspartate Kora Healthcare can be used during pregnancy if clinically needed.

Lactation

Magnesium Aspartate Kora Healthcare can be used during breast-feeding if clinically needed.

Fertility

No effects of magnesium in male and female fertility are anticipated.

4.7 Effects on ability to drive and use machines

Magnesium Aspartate Kora Healthcare has no, or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The assessment of side effects is based on the following frequencies:
Very common (≥1/10);
Common (≥1/100 to <1/10);
Uncommon (≥1/1,000 to <1/100);
Rare (≥1/10,000 to <1/1,000);
Very rare (<1/10,000);
Not known (frequency cannot be estimated from the available data).

MedDRA System Organ Class	Frequency	Undesirable Effects
Gastrointestinal disorders	Uncommon	Soft stools or diarrhoea following high dosage
General disorders and administration site conditions	Very rare	fatigue if used long-term

At high dosage, diarrhoea or gastrointestinal irritation may occur. If it occurs, the daily dose should be reduced and gradually increase later if needed.

Signs of tiredness may occur with high-dose, prolonged use of Magnesium Aspartate Kora Healthcare. This may be an indication that an elevated magnesium level has been achieved. In this case, the dose should be reduced, or the medication should be temporarily discontinued.

Reporting 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 to United Kingdom (Northern Ireland)Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

In addition to the undesirable effects mentioned in section 4.8, no symptoms of intoxication are expected with normal kidney function after overdoses when administered orally.

Only in the case of severe renal insufficiency (serum creatinine > 3.5 mg/100 ml) or anuria can accumulations of magnesium and symptoms of intoxication occur.

In the case of magnesium intoxication, central nervous and cardiac symptoms (influencing atrioventricular conduction and ventricular excitation propagation) and a curare-like effect on neuromuscular conduction can be observed.

Calcium is given iv (100-200 mg calcium $^{2+}$ over 5-10 minutes) as a specific antidote to magnesium intoxication. In addition, hemodialysis, peritoneal dialysis, and ventilation may be required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Mineral Supplements, magnesium

ATC code: A12CC05

Magnesium is a cofactor in >300 enzymatic reactions. It acts as an essential co-factor for all ATP-binding enzymes.

Magnesium plays an important role in cellular electrolyte homeostasis and in the neuromuscular membrane stabilization.

Magnesium:

- acts as a physiological calcium antagonist and as such regulates the contractility of the heart and stabilises cardiac rhythm
- stabilizes the phospholipids of the cell membrane
- inhibits neuromuscular transmission

5.2 Pharmacokinetic properties

Absorption

Intestinal absorption is not directly proportional to magnesium intake but is dependent mainly on magnesium status. The lower the magnesium level, the more magnesium is absorbed in the gut: thus, relative magnesium absorption is high when intake is low and vice versa.

Magnesium is slowly and incompletely absorbed – primarily in the small intestine. The non-absorbable portion can produce a laxative effect.

Peak serum levels are reached after 2-3 hours. At 6h, magnesium absorption is approximately 80% complete.

Distribution

Magnesium is the main intracellular divalent cation, and the normal adult human body content is around 22.6g. About 60% of the magnesium is present in bone, of which 30% is exchangeable and functions as a reservoir to stabilise the serum concentration. About 20% is in skeletal muscle, 19% in other soft tissues and less than 1% in the extracellular fluid.

After oral administration the distribution of magnesium within the body depends on the filling state of magnesium levels in each individual case. The classical method of determining bioavailability using plasma concentration curves cannot be applied to magnesium.

The concentration of magnesium in the blood serum is subject to variations during the day. Due to the equilibrium between magnesium concentration in the blood serum and the depot in the bones, no conclusions concerning the depot in the body can be drawn from the concentration of magnesium in the blood serum. Neuromuscular hyper-excitability can be an indicator of magnesium deficiency.

Elimination

Absorbed magnesium is practically only secreted via the kidney.

Magnesium homeostasis influenced by medication

Diuretics (e.g. thiazide, furosemide) are widely used in the treatment of hypertension, heart failure and kidney diseases. They increase urinary output with hypermagnesuria probably leading to hypomagnesaemia and magnesium depletion.

EGF-receptor antagonist (e.g. cetuximab, erlotinib) are used in the treatment of metastatic colorectal cancer. As EGF is a magnesiotropic hormone, treatment with EGF-receptor antagonists was related to severe hypomagnesaemia.

Long-term treatment with proton pump inhibitors (e.g. omeprazole, pantoprazole) has been related to severe hypomagnesaemia, probably due to disturbances in absorption.

Aminoglycoside antibiotics (e.g. gentamycin, tobramycin) are widely used in the treatment of severe bacterial infections. Studies showed that in 25 % of the patients, hypomagnesaemia occurs due to renal magnesium loss.

Foscarnet is a pyrophosphate analogue that inhibits many viral DNA polymerases.

Hypomagnesaemia is among others a side effect of foscarnet treatment as foscarnet is a potent chelator of divalent cations.

Magnesium homeostasis influenced by medical conditions

Excessive excretion of magnesium into the urine is a cause of magnesium depletion. Osmotic diuresis due to glucosuria can result in magnesium depletion, and diabetes mellitus is probably the most common clinical disorder associated with magnesium depletion. Therefore, diabetics have an increased requirement for magnesium.

Magnesium deficiency has been shown to result in cardiovascular disorders such as cardiac dysrhythmias, which may be manifested by a rapid heart rate (tachycardia), skipped heart beats (premature beats), or a totally irregular cardiac rhythm (fibrillation). A low magnesium status leads to arterial vasoconstriction and thrombocyte aggregation. Migraine patients often show low magnesium levels; therefore, magnesium deficiency seems to play a role in the pathogenesis of migraine. Magnesium supplementation was effective in migraine prophylaxis.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric Acid

Sodium Bicarbonate

Saccharin Sodium

Sorbitol

Apricot–passion fruit flavour containing maltodextrin, gum arabic (E414), 1,2-propylene glycol (E1520), glyceryl triacetate (E1518) and flavouring substance

6.2 Incompatibilities

Not applicable

6.3 Shelf life

30 months.

Shelf life after reconstitution = 24 hours.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Sachet of Paper/ Polyethylene / Aluminium / Polyethylene laminate.

Pack sizes: 20 and 50 sachets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Kora Corporation Ltd. t/a Kora Healthcare

20 Harcourt St
Dublin 2, D02 H364
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

PL 39972/0028

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12/02/2026

10 DATE OF REVISION OF THE TEXT

12/02/2026