

Prescribing Recommendation

Magnesium aspartate dehydrate (Magnaspartate®) for the treatment and prevention of diagnosed magnesium deficiency

Magnesium aspartate dehydrate (Magnaspartate®) equivalent to 243 mg (10 mmol) of magnesium powder for oral solution is the first licensed oral magnesium product available in the UK for the treatment and prevention of magnesium deficiency. Magnesium supplementation has previously been available as a food supplement.¹

Recommendation: Amber0

Magnaspartate® is the preferred choice for the treatment and prevention of magnesium deficiency, as diagnosed by a doctor. It is the only licensed oral magnesium preparation for these indications.

MHRA guidance states “an unlicensed medicinal product may only be supplied in order to meet the special needs of an individual patient. An unlicensed medicinal product should not be supplied where an equivalent licensed medicinal product can meet the special needs of the patient.”² The General Medical Council (GMC) guidance states that unlicensed or off-label medicines should be used only where there is no suitably licensed medicine that will meet the patient's need.

Background

Since magnesium is secreted in large amounts in the gastro-intestinal fluid, excessive losses in diarrhoea, stoma or fistula are the most common causes of hypomagnesaemia; deficiency may also occur in alcoholism or as a result of treatment with certain drugs.* Hypomagnesaemia often causes secondary hypocalcaemia, and also hypokalaemia and hyponatraemia.³

Symptomatic hypomagnesaemia is associated with a deficit of 0.5–1 mmol/kg; up to 160 mmol Mg^{2+} over up to 5 days may be required to replace the deficit (allowing for urinary losses). Magnesium is given initially by intravenous infusion or by intramuscular injection of magnesium sulfate; the intramuscular injection is painful. Plasma magnesium concentration should be measured to determine the rate and duration of infusion and the dose should be reduced in renal impairment.³

To prevent recurrence of the deficit, magnesium may be given by mouth in a dose of 24 mmol Mg^{2+} daily in divided doses, but there is limited evidence of benefit; in addition to the newly licensed magnesium aspartate dehydrate (Magnaspartate®) powder there are magnesium glycerophosphate tablets and liquid [unlicensed] which are available from ‘special-order’ manufacturers or specialist importing companies. For maintenance (e.g. in intravenous nutrition), parenteral doses of magnesium are of the order of 10–20 mmol Mg^{2+} daily (often about 12 mmol Mg^{2+} daily).³

UKMi published a Q&A (111.5) in April 2015 and stated that no national guidelines or fully published studies comparing oral magnesium salts for the prevention of hypomagnesaemia, which evaluated clinical outcomes, were identified.²

A NICE Evidence summary (ESUOM4) in January 2013 summarised the published evidence for the use of magnesium glycerophosphate to prevent the recurrence of symptomatic hypomagnesaemia in people who have already been treated for this condition, generally by intravenous infusion. No clinical trials were found. Only three case reports for this indication in adults were found in which oral magnesium glycerophosphate was not sufficient to maintain normal magnesium levels. No evidence for this indication in children were found.⁴

Costs

| Preparation | Price | Price/mmol |
|--|--------------------------------------|-------------------|
| Licensed preparation: ⁵ Indication: treatment and prevention of magnesium deficiency. Dose; adults 1-2 sachets in 50 – 200 mL water, tea or orange juice daily (dependent on degree of hypomagnesaemia) | | |
| Magnaspartate [®] 243 mg (10 mmol) per 6.5 g peach/apricot flavoured powder for oral solution | 10 sachets = £8.95 | £0.09 |
| Unlicensed preparations (price from part VIIIB of drug tariff): ⁶ | | |
| Magnesium glycerophosphate (magnesium 121.25 mg/5 mL (5 mmol/5 mL)) oral solution | 200 mL - £131.43 | £0.66 |
| Magnesium glycerophosphate (magnesium 121.25 mg/5 mL (5 mmol/5 mL)) oral suspension | 150 mL - £125.21 | £0.83 |
| Magnesium glycerophosphate (magnesium 97.2 mg/5 mL (4 mmol/5mL)) oral solution | 200 mL - £183.08 | £1.14 |
| Magnesium glycerophosphate (magnesium 97.2mg/5ml (4mmol/5ml)) oral suspension | 100 mL - £161.25 | £2.02 |
| Unlicensed preparations (price from HSCIC Prescription Cost analysis, England 2014): ^{2,7} | | |
| Magnesium aspartate granules 121.5mg/6.5 g sachet (5 mmol/sachet) | £1.59/sachet | £0.32 |
| Magnesium aspartate tablets 60.8 mg/tablet (2.5mmol/tablet) | £0.86/tablet | £0.34 |
| Magnesium citrate 1830 mg granules (12 mmol/sachet) | £1.94/sachet | £0.16 |
| Magnesium glycerophosphate chewable 97.2 mg tablets (4 mmol/tablet) | Range; £0.40 - £2.82/chewable tablet | £0.10 - £0.71 |

| | | |
|--|------------------------------|---------------|
| Magnesium glycerophosphate 97.2 mg capsules (4 mmol/capsule) | Range; £2.77 - £3.11/capsule | £0.69 - £1.55 |
| Magnesium glycerophosphate 97.2 mg tablets (4 mmol/tablet) | Range; £1.55 - £2.82/tablet | £0.39 – £0.71 |

Please note these are not the only unlicensed preparations that are available and only an indication of those that can be obtained as special order products. Other preparations available in different salts, forms and/or strengths have similar ranges in price.^{2,7}

NB other forms and brands may be available. There needs to be caution in swapping between preparations on a mmol for mmol basis as they have differing bioavailability and may not have an equivalent therapeutic effect. They need to be titrated to the maximum tolerated dose with monitoring of magnesium serum levels.²

It is important to note that: “Specials are unlicensed medicinal products manufactured in the UK for human use which have been specially prepared to meet a prescription ordered for individual patients without the need for the manufacturer to hold a marketing authorisation for the medicinal product concerned.”²

*The MHRA has drawn attention to an association between hypomagnesaemia and the use of proton pump inhibitors (PPIs).²

Please note a full new medicine review has not been carried out for the production of the above recommendation. This paper provides a summary of the information published by Scottish Medicines Consortium No 1042, NICE Evidence Summary ESUOM4 and UKMi Q&A 111.5.

References

- 1) Scottish Medicines Consortium. Magnesium aspartate dehydrate equivalent to 243 mg (10 mmol) of magnesium powder for oral solution (Magnaspartate). *SMC No. 1042/15*; 6 March 2015 (Issued 5 June 2015).
- 2) UK Medicines Information (South West Medicines Information, Bristol. What oral magnesium preparations are available in the UK and which preparation is preferred for the treatment and prevention of hypomagnesaemia? *Medicines Q&A. 111.5*; 8th April 2015.
- 3) Joint Formulary Committee. British National Formulary. 68th ed. London: British Medical Association and Royal Pharmaceutical Society of Great Britain; August 2015.
- 4) National Institute of Health and Care Excellence. Preventing recurrent hypomagnesaemia: oral magnesium glycerophosphate. *ESUOM4*; 29 January 2013. (updated July 2015).
- 5) Monthly Index of Medical Specialities <http://www.mims.co.uk/> (accessed August 2015)
- 6) National Health Service Drug Tariff for England and Wales, NHS Prescription Services. http://www.ppa.org.uk/ppa/edt_intro.htm (accessed August 2015).
- 7) Health and Social Care Information Centre. Prescription Cost Analysis. England 2014. <http://www.hscic.gov.uk/catalogue/PUB17274/pres-cost-anal-eng-2014-rep.pdf> (accessed August 2015).

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