



HAUTE AUTORITÉ DE SANTÉ

The legally binding text is the original French version

TRANSPARENCY COMMITTEE

OPINION

26 November 2008

Review of product listed for a limited duration in accordance with the decree of October 27, 1999 (Official Journal of October 30, 1999) and the order of December 1, 2006 (JO of December 21, 2006)

UVIMAG B6 oral solution
Pack of 20 vials of 10 ml (CIP: 328 967-9)

Applicant : ZAMBON FRANCE

magnesium hydrogen glycerophosphate
pyridoxine hydrochloride (vitamin B6)

ATC code: A12CC30

Date of validated MA: December 16, 1997, initial MA April 28, 1964

Reason for request: Renewed inclusion on the list of medicines reimbursed by National Insurance.

The provisional opinion issued by the Transparency Committee on June 11, 2008 has been amended subsequent to a review of the actual benefit of products containing magnesium combined with another active ingredient.

1 CHARACTERISTICS OF THE MEDICINAL PRODUCT

1.1. Active ingredient

Magnesium Hydrogen Glycerophosphate, Pyridoxine Hydrochloride

1.2. Indication

“Known magnesium deficiency, isolated or associated.”

1.3. Dosage

2 to 3 vials daily in 2 to 3 doses during meals.

Treatment should be stopped as soon as magnesemia returns to normal

2 REMINDER OF THE COMMITTEE'S OPINION AND LISTING CONDITIONS

Opinion of November 19, 1999

The actual benefit in comparison to other products and treatments available is not sufficient to warrant reimbursement.

Opinion of May 11, 2005

The actual benefit of this product in its indication is moderate.

Opinion of June 11, 2008

The actual benefit of UVIMAG B6 products is:

- moderate, solely in cases of known deficiency induced by a severe enteropathy, tubulopathy.
- insufficient in all other cases.

Provisional opinion pending the reevaluation of magnesium-based products combined with another active ingredient.

3 SIMILAR MEDICINAL PRODUCTS

3.1. ATC Classification (2008)

A	Alimentary tract and Metabolism
A12	Mineral supplements
A12C	Other mineral supplements
A12CC	Magnesium
A12CC30	Magnesium (different salts in combination)

3.2. Medicines in the same therapeutic category

3.2.1. Comparator medicines

Magnesiums combined with vitamin B6:

- MAGNE B6 tablets (magnesium pidolate, magnesium lactate dihydrate, pyridoxine hydrochloride)
- MAGNESIUM VITAMIN B6 BIOGARAN tablets

3.3. Medicines with a similar therapeutic aim

Products containing magnesium salts only:

- EFIMAG sachets (magnesium pidolate)
- MAG 2 (magnesium pidolate)
- MEGAMAG 45 mg capsules (magnesium aspartate)

4 UPDATING WITH DATA OBTAINED SINCE PREVIOUS OPINION

In the context of a reevaluation of products containing a combination of magnesium with another active ingredient, the company was called upon to justify the benefit of a combination of a magnesium salt with vitamin B6.

None of the studies submitted establish the actual benefit of the combination of magnesium salt with vitamin B6.

5 DRUG USAGE DATA

According to IMS data (CMA August 2008), 50,000 prescriptions of UVIMAG B6 have been delivered. The most common reasons for prescription were malaise and fatigue (41%). The average daily dosage is 2.4 units. Therefore, in at least half of cases, the prescription is outside the scope of the MA.

6 TRANSPARENCY COMMITTEE CONCLUSIONS

6.1. Reassessment of the actual benefit

Known magnesium deficiency, i.e. confirmed by labwork, corresponds essentially to chronic situations, the cause of which may be digestive (severe enteropathy) or nephrological (tubulopathy). These situations must be managed with a magnesium salt in the long term. A known magnesium deficiency can cause mental, cardiovascular, neuromuscular or electrolyte disorders. In some cases it can progress towards a deterioration in the quality of life or a disability.

There is no proof of the efficacy of a combination of magnesium salt with vitamin B6 compared to magnesium salt alone. The efficacy/adverse effects ratio has not been established.

This product is used as a form of symptomatic treatment.

Magnesium salt-vitamin B6 combinations are not therapeutically relevant for magnesium deficiency.

The public health burden of advanced magnesium deficiency is minor. These clinical situations do not constitute a public health need.

In light of available data on known magnesium deficiency, no impact is expected from these products at population level in terms of morbidity and mortality or quality of life.

For this reason, these products are not expected to benefit public health.

The actual benefit of UVIMAGE B6 oral solution is not sufficient enough to be covered by national solidarity.

6.2. Therapeutic use

Apart from known magnesium deficiencies due to digestive or renal problems, it is not appropriate to prescribe magnesium.

There is no proof of the actual benefit of a combination of magnesium salt with vitamin B6 compared to magnesium salt alone.

6.3. Transparency Committee recommendations

The Transparency Committee does not recommend the inclusion of UVIMAG B6 oral solution on the list of medicines reimbursed by National Insurance.