



HAUTE AUTORITÉ DE SANTÉ

The legally binding text is the original French version

## TRANSPARENCY COMMITTEE

### OPINION

26 November 2008

Examination of the dossier of the medicinal product included on the reimbursement list for a limited duration pursuant to the Decree of 27 October 1999 (published on 30 October 1999) and the Order of 1 December 2006 (published on 21 December 2006).

**MAGNESIUM VITAMIN B6 BIOGARAN 470 mg/5 mg, film-coated tablet**  
**Pack of 50 tablets (CIP: 385 358-8)**

**Applicant: BIOGARAN**

Magnesium lactate dihydrate  
Pyridoxine hydrochloride (vitamin B6)

Marketing authorisation (MA) date: 22 April 2008

Reason for request: Renewal of inclusion on the list of reimbursable medicinal products.

The provisional opinion issued on 11 June 2008 by the Transparency Committee was modified following the reassessment of the actual benefit of proprietary medicines containing magnesium in combination with another active ingredient.

Medical and Economic Evaluation and Public Health Division

## 1 CHARACTERISTICS OF THE MEDICINAL PRODUCT

### 1.1. Active ingredient

Magnesium lactate dihydrate

Pyridoxine hydrochloride (vitamin B6)

### 1.2. Indications

“Established magnesium deficiencies, whether isolated or associated with other deficiencies.”

### 1.3. Dosage

The dosage is:

- In adults: 6 to 8 tablets per day,
- In children over 6 years (approximately 20kg) : 4 to 6 tablets per day.

## 2 REMINDER OF THE COMMITTEE'S OPINION AND LISTING CONDITIONS

Opinion of 11 June 2008

The actual benefit of the proprietary medicines MAGNESIUM VITAMINE B6 BIOGARAN is:

- moderate only in established deficiencies secondary to severe enteropathy, tubulopathy or nephrotic syndrome.
- insufficient in the other cases.

Provisional opinion pending the reassessment of proprietary medicines containing magnesium in combination with another active ingredient.

## 3 SIMILAR MEDICINAL PRODUCTS

### 3.1. ATC Classification (2008)

A	Alimentary tract and metabolism
A12	Mineral supplement
A12C	Other mineral supplements
A12CC	Magnesium
A12CC06	Magnesium lactate

### 3.2. Medicines in the same therapeutic category

These are preparations combining magnesium with vitamin B6:

- MAGNE B6 tablet (magnesium pidolate, magnesium lactate dihydrate, pyridoxine hydrochloride);
- UVIMAG B6 vial (magnesium hydrogen glycerophosphate, pyridoxine hydrochloride).

### 3.3. Medicines with a similar therapeutic aim

These are proprietary medicines containing magnesium salts alone:

- EFIMAG, sachets (magnesium pidolate),
- MAG 2 (magnesium pidolate),
- MEGAMAG 45mg, capsule (magnesium aspartate).

#### 4 UPDATING WITH DATA OBTAINED SINCE THE PREVIOUS OPINION

Within the scope of the reassessment of proprietary medicines containing a combination of magnesium with another active ingredient, the company was asked to justify the therapeutic use of the combination of a magnesium salt with vitamin B6.

As this proprietary medicine is extremely similar to MAGNE B6, no study was presented.

#### 5 DRUG USAGE DATA

This medicinal product is no longer marketed.

#### 6 TRANSPARENCY COMMITTEE CONCLUSIONS

##### 6.1. Reassessment of actual benefit

Established, i.e. biologically confirmed, magnesium deficiencies, mainly occur during chronic gastrointestinal (severe enteropathy) or renal disorders (tubulopathy or nephrotic syndrome). These disturbances must be treated by long-term administration of a magnesium salt. Overt magnesium deficiency may cause mental, cardiovascular, neuromuscular or electrolyte disorders. In certain cases, these may progress and cause deterioration in quality of life or disability.

There is no evidence that a combination of a magnesium salt and vitamin B6 is more effective than magnesium alone. The efficacy/safety ratio has not been established.

This proprietary drug is intended for symptomatic treatment.

Combinations of magnesium salts and vitamin B6 have no place in the therapeutic management of magnesium deficiency.

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

An assessment of the available data on overt magnesium deficiencies suggests that these medicines will not impact population health outcomes in terms of morbidity and mortality or quality of life.

Consequently, these products are not expected to benefit public health.

The actual benefit of MAGNESIUM VITAMIN B6 BIOGARAN, is insufficient for reimbursement by national solidarity.

##### 6.2. Therapeutic use

Apart from overt deficiencies of gastrointestinal or renal origin, there is no need to prescribe magnesium.

There is no evidence that products containing magnesium combined with vitamin B6 have any clinical benefit compared to magnesium alone.

### **6.3. Transparency Committee recommendations**

The Transparency Committee recommends to remove MAGNE B6 from the list of products reimbursed by National Insurance.