



HAUTE AUTORITÉ DE SANTÉ

The legally binding text is the original French version

TRANSPARENCY COMMITTEE

OPINION

2 December 2009

PRINCI B film-coated tablets
Pack of 30 tablets (CIP: 341 886-9)

Applicant: SERP

Thiamine / pyridoxine

ATC Code: A11DB

MA date: MA validated October 4, 1997, initial authorisation October 21, 1976

Reason for request: inclusion on the list of medicines approved for use by hospitals.

1 CHARACTERISTICS OF THE MEDICINAL PRODUCT

1.1. Active ingredient

Thiamine, Pyridoxine

1.2. Indication

“Adjunctive treatment of functional asthenia.”

1.3. Dosage

1 to 3 tablets per day

Treatment duration is limited to 4 weeks.

2 SIMILAR MEDICINAL PRODUCTS

2.1. ATC Classification (2009)

A : Alimentary tract and metabolism
A11 : Vitamins
A11D : Vitamin B plain and in combination with vitamins B6 and B12
A11DB : Vitamin B1 in combination with vitamin B6 and/or B12

2.2. Medicines in the same therapeutic category

Vitamin B1 B6 BAYER film-coated tablets are approved for use by hospitals in adjunctive treatment of functional asthenia.

Plain vitamin B1-based products are approved for use by hospitals in the treatment of vitamin B1 deficiency (beriberi) and in Wernicke’s encephalopathy.

Vitamin B1
BENERVA coated tablets
BENERVA solution for injection
BEVITINE coated tablets
BEVITINE solution for injection

Vitamin B6
Plain vitamin B6-based products are approved for use by hospitals in the treatment of known vitamin B6 deficiencies.
BECILAN scored tablets
BECILAN solution for injection
Vitamin B6 AGUETTANT solution for injection
PYRIDOXINE RENAUDIN solution for injection

2.3. Medicines with a similar therapeutic aim

All medicinal products for the treatment of functional asthenia. These include a number of vitamins, amino acids, and trace elements not approved for use by hospitals.

3 ANALYSIS OF AVAILABLE DATA

The company has provided no study, even bibliographical, in the indication of adjunctive treatment of functional asthenia.

The safety data available, although limited, does not reveal any recent safety signs. Furthermore, the SPC's adverse effects section indicates exceptional reversible neurological symptoms after strong or prolonged doses of vitamin B6. In addition, PRINCI B is contraindicated in combination with levodopa.

No PSUR has been submitted.

4 TRANSPARENCY COMMITTEE CONCLUSIONS

4.1. Actual benefit

Functional asthenia is a symptom that can be induced by a number of pathological or non-pathological conditions.

The advantage of a combination of vitamin B1 and B6 in functional asthenia has not been established.

At the usual dosages, this product does not appear to expose patients to serious and/or frequent adverse effects.

The combination of vitamin B1 and B6 is an adjunctive treatment.

PRINCI B is not expected to benefit public health in this indication.

The actual benefit of PRINCI B in the indication "adjunctive treatment of functional asthenia" is not sufficient to warrant being covered by national solidarity.

4.2. Therapeutic use

Functional asthenia is a symptom that can be induced by a number of pathological or non-pathological conditions. Its therapeutic use depends on the cause of asthenia.

The combination of vitamin B1 and B6 has no particular therapeutic use for functional asthenia.

4.3. Transparency Committee recommendations

The Transparency Committee does not recommend inclusion on the list of medicines approved for use by hospitals and various public services in the MA indications.

The committee wishes to review the actual clinical benefit of vitamin B1 and B6 combinations approved for use by hospitals in the indication "adjunctive treatment of functional asthenia".