



HAUTE AUTORITÉ DE SANTÉ

The legally binding text is the original French version

TRANSPARENCY COMMITTEE

OPINION

12 November 2008

EBIXA 20 mg film-coated tablets

B/28 CIP: 387 403-0

B/98 CIP: 573 705-3

Applicant: LUNDBECK

Memantine hydrochloride

List I

Drugs available on restricted medical prescription:

- initial annual prescription by doctors specialised in neurology or in psychiatry, by specialist doctors with a complementary certificate in geriatrics and by specialist or general doctors qualified in gerontology.
- medicinal product requiring specific monitoring during treatment

Date of European marketing authorisation (centralised procedure): 8 May 2008

ATC Code: N06DX01 (anti-dementia drugs)

Reason for request: inclusion on list of products reimbursed by National Insurance (B/28 and B/98) and for use in hospitals (B/98) in addition to EBIXA 10 mg tablets and EBIXA 10 mg/g oral drops, solution.

Indication: "*Treatment of patients with moderate to severe Alzheimer's disease.*"

The actual benefit of this proprietary drug is substantial.

This product is an addition to the range of treatments, which does not provide any improvement in actual benefit.

The Transparency Committee recommends inclusion on the list of medicines reimbursed by National Insurance (B/28 and B/98) and on the list of medicines approved for use by hospitals and various public services (B/98) in the indications and at the dosage given in the marketing authorisation.

Packaging: not appropriate for the prescription conditions.

- The Committee notes that, in line with its deliberations of 20 July 2005, it recommends that packaging size for 1-month courses of treatment be harmonised at 30 days, and that as a result packaging size of 90 days be provided for three-month courses of treatment.
- The Committee wishes to state that the three-month package size (B/98) is appropriate for clinical situations in which prolonged courses of treatment are required and for patients whose condition is stable.

Reimbursement rate: 65%.