

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

LATUDA (lurasidone), oral antipsychotic

No clinical benefit demonstrated in the treatment of schizophrenia in adults compared with existing antipsychotics

Main points

- ▶ LATUDA has Marketing Authorisation for the treatment of schizophrenia in adults.
- ▶ It is an alternative to antipsychotics that are currently available. The clinical data (studies versus placebo and non-inferiority studies) have not demonstrated an advantage compared with the available alternatives.

Therapeutic use

Antipsychotics are the standard treatment for schizophrenia. They are used in the treatment of the acute phase and in the prevention of relapses.

■ Role of the medicinal product in the therapeutic strategy

LATUDA is a new alternative to other oral antipsychotics indicated in the treatment of schizophrenia.

Clinical data

- In the treatment of exacerbations of schizophrenia, the short-term efficacy of lurasidone in the reduction of psychotic symptoms has been demonstrated over 6 weeks in the course of three studies versus placebo at fixed doses between 37 and 148 mg/day.
- Its efficacy in the prevention of relapses, in maintenance therapy in schizophrenia, has been evaluated in the course of three clinical studies:
 - in a 28-week "treatment discontinuation" study versus placebo with a duration of 28 weeks, the patients treated with lurasidone had a significantly lower probability of relapse (42.2%) compared with patients who were given the placebo (51.2%) (HR: 0.66; 95% CI [0.45 to 0.98]);
 - in a 12-month non-inferiority study versus risperidone, the probability of relapse was 26.5% in the lurasidone group and 21.0% in the risperidone group (HR: 1.31; 95% CI [0.87 to 1.97]). It is not possible to conclude the non-inferiority of lurasidone compared with risperidone;
 - in a 12-month study versus quetiapine, the probability of relapse was 23,6 % in the lurasidone group and 33,6% in the quetiapine group (HR: 0.728; 95% CI [0.410 to 1.295]).
- The adverse events most often reported among patients treated with lurasidone were akathisia, drowsiness, and sedation.

Benefit of the medicinal product

- The actual benefit* of LATUDA is substantial.
- LATUDA does not provide any clinical added value** (CAV V, none) in the treatment of schizophrenia in adults.
- The Transparency Committee recommends inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.



HAUTE AUTORITÉ DE SANTÉ

This document was created on the basis of the Transparency Committee Opinion of 19 November 2014 (CT-13782) and is available at www.has-sante.fr

* The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement by National Health Insurance.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means “no clinical added value”.