



23 January 2014
EMA/CHMP/26583/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Latuda lurasidone

On 23 January 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Latuda, 18.5 mg, 37 mg and 74 mg, film-coated tablet intended for the treatment of schizophrenia in adults aged 18 years and over. The applicant for this medicinal product is Takeda Pharma A/S. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Latuda is lurasidone, an antipsychotic (ATC Code N05AE05) blocking dopamine and monoamine effects. Lurasidone binds primarily to dopaminergic D2- and to serotonergic 5-HT_{2A} and 5-HT₇- receptors. By doing so it affects the activity of the brain and reduces symptoms of schizophrenia (psychotic symptoms).

The benefits with Latuda are its ability to improve psychotic symptoms. Latuda tablets were more effective than placebo in reducing the symptoms of the disease. The most common side effects are akathisia and somnolence.

A pharmacovigilance plan for Latuda will be implemented as part of the marketing authorisation.

The approved indication is: "the treatment of schizophrenia in adults aged 18 years and over ". It is proposed that Latuda be prescribed by physicians experienced in the treatment of schizophrenia.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Latuda and therefore recommends the granting of the marketing authorisation.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

