18 March 2010
Doc. Ref.: EMA/148993/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Olanzapine Apotex

olanzapine

On 18 March 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Olanzapine Apotex 2.5 mg, 5 mg, 7.5 mg and 10 mg, film-coated tablets and Olanzapine Apotex 5 mg, 10 mg, 15 mg and 20 mg orodispersible tablets, intended for the treatment of schizophrenia. The applicant for this medicinal product is Apotex Europe BV.

The active substance of Olanzapine Apotex is olanzapine, an atypical antipsychotic (N05AH03).

Olanzapine Apotex is a generic of Zyprexa which has been authorised in the EU since 27 September 1996. Studies have demonstrated the satisfactory quality of Olanzapine Apotex, and its bioequivalence with Zyprexa. A question-and-answer document on generic medicines can be found here.

The approved indication is: “Olanzapine is indicated for the treatment of schizophrenia. Olanzapine is effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. Olanzapine is indicated for the treatment of moderate to severe manic episode. In patients whose manic episode has responded to olanzapine treatment, olanzapine is indicated for the prevention of recurrence in patients with bipolar disorder”.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of the data submitted, considers that there is a favourable benefit to risk balance for Olanzapine Apotex, 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.

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