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Public statement

Olanzapine Cipla

Withdrawal of the marketing authorisation in the European Union

On 8 July 2014, the European Commission withdrew the marketing authorisation for Olanzapine Cipla (olanzapine) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Cipla EU Ltd, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Olanzapine Cipla was granted marketing authorisation in the EU on 14 November 2007 for the treatment of adults with schizophrenia. It was also authorised to treat moderate to severe manic episodes in adults and in the prevention of recurrence of these episodes in adults with bipolar disorder. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2012.

Olanzapine Cipla is a generic medicine of Zyprexa. There are other generic medicinal products of Zyprexa authorised and marketed in the EU.

The European Public Assessment Report (EPAR) for Olanzapine Cipla will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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