European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

OLANZAPINE MYLAN

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Olanzapine Mylan?

Olanzapine Mylan is a medicine containing the active substance olanzapine. It is available as white tablets (round: 2.5, 5, 7.5 and 10 mg; oval: 15 and 20 mg).
Olanzapine Mylan is a 'generic medicine'. This means that Olanzapine Mylan is similar to a 'reference medicine' already authorised in the European Union (EU) called Zyprexa. For more information on generic medicines, see the question-and-answer document here.

What is Olanzapine Mylan used for?

Olanzapine Mylan is used to treat adults with schizophrenia. Schizophrenia is a mental illness that has a number of symptoms, including disorganised thinking and speech, hallucinations (hearing or seeing things that are not there), suspiciousness and delusions (mistaken beliefs). Olanzapine Mylan is also effective in maintaining improvement in patients who have responded to an initial course of treatment.
Olanzapine Mylan is also used to treat moderate to severe manic episodes (extremely high mood) in adults. It can also be used to prevent the recurrence (when symptoms come back) of these episodes in adults with bipolar disorder (a mental illness with alternating periods of high mood and depression) who have responded to an initial course of treatment.
The medicine can only be obtained with a prescription.

How is Olanzapine Mylan used?

The recommended starting dose of Olanzapine Mylan tablets depends on the disease being treated: 10 mg per day is used in schizophrenia and in the prevention of manic episodes, and 15 mg per day in the treatment of manic episodes, unless it is used with other medicines, in which case the starting dose can be 10 mg per day. The dose is adjusted depending on how well the patient responds to and tolerates the treatment. The usual dose range is between 5 and 20 mg per day. Patients over 65 years of age and patients who have problems with their liver or kidneys may need a lower starting dose of 5 mg per day. Olanzapine Mylan is not recommended for use in patients below 18 years of age because of a lack on information on safety and effectiveness in this age group.

How does Olanzapine Mylan work?

The active substance in Olanzapine Mylan, olanzapine, is an antipsychotic medicine. It is known as an 'atypical' antipsychotic because it is different from the older antipsychotic medicines that have been available since the 1950s. Its exact mechanism of action is unknown, but it attaches to several

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receptors on the surface of nerve cells in the brain. This disrupts signals transmitted between brain cells by 'neurotransmitters', chemicals that allow nerve cells to communicate with each other. It is thought that olanzapine's beneficial effect is due to it blocking receptors for the neurotransmitters 5-hydroxytrypamine (also called serotonin) and dopamine. Since these neurotransmitters are involved in schizophrenia and in bipolar disorder, olanzapine helps to normalise the activity of the brain, reducing the symptoms of these diseases.

How has Olanzapine Mylan been studied?
Because Olanzapine Mylan is a generic medicine, studies have been limited to tests to demonstrate that it is bioequivalent to the reference medicine (i.e. that the two medicines produce the same levels of the active substance in the body).

What is the risk associated with Olanzapine Mylan?
Because Olanzapine Mylan is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as those of the reference medicine.

Why has Olanzapine Mylan been approved?
The Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Olanzapine Mylan has been shown to have comparable quality and to be bioequivalent to Zyprexa. Therefore, the CHMP's view was that, as for Zyprexa, the benefit outweighs the identified risk. The Committee recommended that Olanzapine Mylan be given marketing authorisation.

Other information about Olanzapine Mylan:
The European Commission granted a marketing authorisation valid throughout the European Union for Olanzapine Mylan to Generics [UK] Ltd. on 7 October 2008.

The full EPAR for Olanzapine Mylan can be found here.
The full EPAR for the reference medicine can also be found on the EMEA's website.

This summary was last updated in 08-2008.