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EPAR summary for the public

Olanzapine Glenmark Europe

Olanzapine

This is a summary of the European public assessment report (EPAR) for Olanzapine Glenmark Europe. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Olanzapine Glenmark Europe.

What is Olanzapine Glenmark Europe?

Olanzapine Glenmark Europe is a medicine containing the active substance olanzapine. It is available as orodispersible tablets (5, 10, 15 and 20 mg). Orodispersible tablets are tablets that dissolve in the mouth.

Olanzapine Glenmark Europe is a 'generic medicine'. This means that Olanzapine Glenmark Europe is similar to 'reference medicines' already authorised in the European Union (EU) called Zyprexa and Zyprexa Velotabs. For more information on generic medicines, see the question-and-answer document here.

What is Olanzapine Glenmark Europe used for?

Olanzapine Glenmark Europe 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 Glenmark Europe is also effective in maintaining improvement in patients who have responded to an initial course of treatment.

Olanzapine Glenmark Europe is also used to treat moderate to severe manic episodes (extremely high mood) in adults. It can also be used to prevent the recurrence of these episodes (when symptoms come back) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

The medicine can only be obtained with a prescription.

How is Olanzapine Glenmark Europe used?

The recommended starting dose of Olanzapine Glenmark Europe 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 according to how well the patient responds to and tolerates the treatment. The usual dose range is between 5 and 20 mg per day. The orodispersible tablets are taken by being placed on the tongue, where they disintegrate in the saliva, or by mixing them in water before swallowing. 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.

How does Olanzapine Glenmark Europe work?

The active substance in Olanzapine Glenmark Europe, 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 different 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-hydroxytryptamine (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 Glenmark Europe been studied?

Because Olanzapine Glenmark Europe is a generic medicine, studies have been limited to tests to determine that it is bioequivalent to the reference medicines, Zyprexa and Zyprexa Velotab. Medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Olanzapine Glenmark Europe?

Because Olanzapine Glenmark Europe is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as the reference medicines.

Why has Olanzapine Glenmark Europe been approved?

The CHMP concluded that, in accordance with EU requirements, Olanzapine Glenmark Europe has been shown to have comparable quality and to be bioequivalent to Zyprexa and Zyprexa Velotab. Therefore, the CHMP's view was that, as for Zyprexa and Zyprexa Velotab, the benefit outweighs the identified risk. The Committee recommended that Olanzapine Glenmark Europe be given marketing authorisation.

Other information about Olanzapine Glenmark Europe

The European Commission granted a marketing authorisation valid throughout the EU for Olanzapine Glenmark Europe on 3 December 2009.

The full EPAR for Olanzapine Glenmark Europe can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more

information about treatment with Olanzapine Glenmark Europe, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicines can also be found on the Agency's website.

This summary was last updated in 01-2013.