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EPAR summary for the public

Olanzapine Teva

olanzapine

This is a summary of the European public assessment report (EPAR) for Olanzapine Teva. 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 Teva.

What is Olanzapine Teva?

Olanzapine Teva is a medicine containing the active substance olanzapine. It is available as tablets (2.5, 5, 7.5, 10, 15 and 20 mg) and as 'orodispersible' tablets (5, 10, 15 and 20 mg). Orodispersible tablets are tablets that dissolve in the mouth.

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

What is Olanzapine Teva used for?

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

Olanzapine Teva 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 causing 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.

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How is Olanzapine Teva used?

The recommended starting dose of Olanzapine Teva 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. The orodispersible tablets, which can be used as an alternative to the tablets, are taken by being placed on the tongue, where they disintegrate quickly 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 Teva work?

The active substance in Olanzapine Teva, 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 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 bipolar disorder, olanzapine helps to normalise the activity of the brain, reducing the symptoms of these diseases.

How has Olanzapine Teva been studied?

Because Olanzapine Teva is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicines. Two medicines are bioequivalent when produce the same levels of the active substance in the body.

What are the benefits and risks of Olanzapine Teva?

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

Why has Olanzapine Teva been approved?

The CHMP concluded that, in accordance with EU requirements, Olanzapine Teva 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 Teva be given marketing authorisation.

Other information about Olanzapine Teva

The European Commission granted a marketing authorisation valid throughout the European Union for Olanzapine Teva on 12 December 2007.

The full EPAR for Olanzapine Teva 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 Teva, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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

This summary was last updated in 11-2012.