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EPAR summary for the public

Olanzapine Apotex

olanzapine

This document is a summary of the European Public Assessment Report (EPAR) for Olanzapine Apotex. 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 Apotex.

What is Olanzapine Apotex?

Olanzapine Apotex is a medicine containing the active substance olanzapine. It is available as white, round film-coated tablets (2.5, 5, 7.5 and 10 mg) and yellow, round orodispersible tablets (5, 10, 15 and 20 mg). Orodispersible tablets are tablets that dissolve in the mouth.

Olanzapine Apotex is a 'generic medicine'. This means that Olanzapine Apotex 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 Apotex used for?

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

Olanzapine Apotex 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.

The medicine can only be obtained with a prescription.

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How is Olanzapine Apotex used?

The recommended starting dose of Olanzapine Apotex 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 Apotex work?

The active substance in Olanzapine Apotex, 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-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 Apotex been studied?

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

What are the benefit and risk of Olanzapine Apotex?

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

Why has Olanzapine Apotex been approved?

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

Other information about Olanzapine Apotex:

The European Commission granted a marketing authorisation valid throughout the EU for Olanzapine Apotex to Apotex Europe B.V. on 10 June 2010. The marketing authorisation is valid for five years, after which it can be renewed.

The full EPAR for Olanzapine Apotex can be found here. For more information about treatment with Olanzapine Apotex, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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

This summary was last updated in 04-2010.