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EPAR summary for the public

Zyprexa

olanzapine

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

What is Zyprexa?

Zyprexa 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 a powder to be made up into a solution for injection.

What is Zyprexa used for?

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

Zyprexa 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.

Zyprexa is usually taken by mouth as tablets, but the injection can be used for the rapid control of agitation or disturbed behaviour in adults with schizophrenia or a manic episode, when taking the medicine by mouth is not appropriate.

The medicine can only be obtained with a prescription.

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How is Zyprexa used?

The recommended starting dose of Zyprexa 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 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 usual dose when using the injection is 10 mg as a single injection into a muscle. This can be followed if needed by a further injection of 5 or 10 mg two hours later.

Lower doses may be needed for patients over 65 years of age (5 mg per day for the tablets and 2.5 to 5 mg for the injection) and for patients who have reduced liver or kidney function (5 mg per day for both the tablets and injection).

In all cases, the maximum dose of Zyprexa that can be given in a day, using tablets or injection, is 20 mg.

How does Zyprexa work?

The active substance in Zyprexa, 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 Zyprexa been studied?

In schizophrenia, Zyprexa tablets have been studied in about 3,000 adults, in which their effectiveness was compared with that of placebo (a dummy treatment) or haloperidol (another antipsychotic medicine). All four studies lasted six weeks, but the patients stayed on the medicine for up to a year or more.

In the treatment of acute manic episodes in adults with bipolar disorder, Zyprexa tablets were compared with placebo, haloperidol or valproate (another medicine used in manic episodes) in five studies, including one where patients were also receiving other medicines. In the prevention of manic episodes, Zyprexa tablets were studied in 1,162 adults. Their effectiveness was compared with that of placebo or lithium (another medicine used in bipolar disorder).

The injection was studied in 581 adults with schizophrenia (compared with placebo or injected haloperidol) and 228 manic adults (compared with placebo or injected lorazepam, another medicine used in manic episodes).

In all studies, the effectiveness of Zyprexa was assessed using various symptom-rating scales.

What benefit has Zyprexa shown during the studies?

In all studies, Zyprexa as tablets and as injections was more effective at improving symptoms than placebo. Zyprexa tablets were at least as effective as the medicines they were compared with for the treatment of schizophrenia (haloperidol), the treatment of moderate to severe manic episodes

(haloperidol and valproate), and the prevention of recurrence in patients with bipolar disorder (lithium). The injection was also shown to be more effective than lorazepam (at a relatively low dose) in manic patients, and as effective as haloperidol in schizophrenia.

What is the risk associated with Zyprexa?

The most common side effects with Zyprexa (seen in more than 1 patient in 10) are somnolence (sleepiness), weight gain, orthostatic hypotension (sudden drop in blood pressure on standing up) and raised levels of prolactin (a hormone). For the full list of all side effects reported with Zyprexa, see the package leaflet.

Zyprexa must not be used in people who are hypersensitive (allergic) to olanzapine or any of the other ingredients. It must also not be used in patients at risk of narrow-angle glaucoma (raised pressure inside the eye).

Why has Zyprexa been approved?

The CHMP decided that Zyprexa's benefits are greater than its risks and recommended that Zyprexa be given marketing authorisation.

Other information about Zyprexa

The European Commission granted a marketing authorisation valid throughout the European Union for Zyprexa on 27 September 1996.

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

This summary was last updated in 05-2013.