



EUROPEAN MEDICINES AGENCY  
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## EPAR summary for the public

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# Olazax

## olanzapine

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

### What is Olazax?

Olazax is a medicine containing the active substance olanzapine. It is available as tablets (5, 7.5 10, 15 and 20 mg).

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

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

Olazax 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.



## How is Olazax used?

The recommended starting dose of Olazax 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. Patients over 65 years of age and patients who have reduced liver or kidney function may need a lower starting dose of 5 mg per day.

## How does Olazax work?

The active substance in Olazax, 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 Olazax been studied?

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

## What are the benefits and risks of Olazax shown during the studies?

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

## Why has Olazax been approved?

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

## Other information about Olazax

The European Commission granted a marketing authorisation valid throughout the EU for Olazax on 11 December 2009.

The full EPAR for Olazax can be found on the Agency's website: [ema.europa.eu/Find\\_medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports). For more information about treatment with Olazax, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist. This summary was last updated in 07-2014.