European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

ZALASTA

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Zalasta?

Zalasta is a medicine containing the active substance olanzapine. It is available as round, yellow tablets (2.5, 5, 7.5, 10, 15 and 20 mg) and as round, yellow 'orodispersible' tablets (5, 7.5, 10, 15 and 20 mg). Orodispersible tablets are tablets that dissolve in the mouth.
Zalasta is a 'generic medicine'. This means that Zalasta 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 Zalasta used for?

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

How is Zalasta used?

The recommended starting dose of Zalasta 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 Zalasta work?

The active substance in Zalasta, 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

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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 Zalasta been studied?
Because Zalasta is a generic medicine, studies have been limited to tests to demonstrate that it is bioequivalent to the reference medicines (i.e. that the medicines produce the same levels of the active substance in the body).

What are the benefit and risk of Zalasta?
Because Zalasta 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 Zalasta been approved?
The Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Zalasta 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 Zalasta be given marketing authorisation.

Other information about Zalasta:
The European Commission granted a marketing authorisation valid throughout the EU for Zalasta to KRKA, d.d., Novo mesto on 27 September 2007.

The full EPAR for Zalasta can be found here.
The full EPARs for the reference medicines can also be found on the EMEA's website.

This summary was last updated in 09-2008.