



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/407132/2013
EMA/H/C/000287

EPAR summary for the public

Zyprexa Velotab

olanzapine

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

What is Zyprexa Velotab?

Zyprexa Velotab is a medicine that contains the active substance olanzapine. It is available as 'orodispersible' tablets (5, 10, 15 and 20 mg). Orodispersible tablets are tablets that dissolve in the mouth.

What is Zyprexa Velotab used for?

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

Zyprexa Velotab 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 Zyprexa Velotab used?

The recommended starting dose of Zyprexa Velotab 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 quickly in the saliva, or by mixing them in water before swallowing. 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 Zyprexa Velotab work?

The active substance in Zyprexa Velotab, 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 Zyprexa Velotab been studied?

Zyprexa Velotab contains the same active substance as another medicine called Zyprexa that has been authorised in the European Union (EU) since 1996. Because of this, the studies done with Zyprexa were used to support the use of Zyprexa Velotab. Three studies were also carried to show that, when taken by mouth, the two medicines produce equivalent levels of olanzapine in the blood.

What benefit has Zyprexa Velotab shown during the studies?

Like Zyprexa, Zyprexa Velotab was more effective at improving symptoms than placebo (a dummy treatment). Zyprexa Velotab was as effective as the medicines that it was compared with for the treatment of adults with schizophrenia, the treatment of moderate to severe manic episodes in adults, and the prevention of recurrence in adults with bipolar disorder.

What is the risk associated with Zyprexa Velotab?

The most common side effects with Zyprexa Velotab (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 Velotab, see the package leaflet.

Zyprexa Velotab 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 Velotab been approved?

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

Other information about Zyprexa Velotab

The European Commission granted a marketing authorisation valid throughout the European Union for Zyprexa Velotab on 3 February 2000.

The full EPAR for Zyprexa Velotab 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%20medicines/European%20public%20assessment%20reports). For more information about treatment with Zyprexa Velotab, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2013.