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Olanzapine Viatris[1] (*olanzapine*)

An overview of Olanzapine Viatris and why it is authorised in the EU

What is Olanzapine Viatris and what is it used for?

Olanzapine Viatris is used to treat adults with schizophrenia. Schizophrenia is a mental illness with symptoms such as delusions, disorganised thinking and speech, suspiciousness and hallucinations (seeing, hearing or feeling things that are not there).

Olanzapine Viatris is also used to treat moderate to severe manic episodes (extremely high mood) in adults. It can also be used to prevent the recurrence (when symptoms come back) of these episodes 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.

Olanzapine Viatris contains the active substance olanzapine and is a 'generic medicine'. This means that Olanzapine Viatris contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Olanzapine Viatris is Zyprexa. For more information on generic medicines, see the question-and-answer document here.

How is Olanzapine Viatris used?

Olanzapine Viatris is available as tablets and is taken once a day. The dose depends on the disease being treated and may be adjusted depending on how well the patient responds to and tolerates the treatment.

The medicine can only be obtained with a prescription.

For more information about using Olanzapine Viatris, see the package leaflet or contact your doctor or pharmacist.

How does Olanzapine Viatris work?

The active substance in Olanzapine Viatris, 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

[1] Previously known as Olanzapine Mylan.

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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 Viatris been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Zyprexa, and do not need to be repeated for Olanzapine Viatris.

As for every medicine, the company provided studies on the quality of Olanzapine Viatris. The company also carried out studies that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Olanzapine Viatris?

Because Olanzapine Viatris is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Olanzapine Viatris authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Olanzapine Viatris has been shown to have comparable quality and to be bioequivalent to Zyprexa. Therefore, the Agency's view was that, as for Zyprexa, the benefits of Olanzapine Viatris outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Olanzapine Viatris?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Olanzapine Viatris have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Zyprexa also apply to Olanzapine Viatris where appropriate.

As for all medicines, data on the use of Olanzapine Viatris are continuously monitored. Suspected side effects reported with Olanzapine Viatris are carefully evaluated and any necessary action taken to protect patients.

Other information about Olanzapine Viatris

Olanzapine Mylan received a marketing authorisation valid throughout the EU on 7 October 2008.

The name of the medicine was changed to Olanzapine Viatris on 15 October 2024.

Further information on Olanzapine Viatris can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/olanzapine-viatris. Information on the reference medicine can also be found on the Agency's website.

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