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EPAR summary for the public

Latuda

lurasidone

This is a summary of the European public assessment report (EPAR) for Latuda. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Latuda.

For practical information about using Latuda, patients should read the package leaflet or contact their doctor or pharmacist.

What is Latuda and what is it used for?

Latuda is a medicine that contains the active substance lurasidone. It is used to treat adults with schizophrenia, 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).

How is Latuda used?

Latuda is available as tablets (18.5, 37 and 74 mg) and can only be obtained with a prescription. The recommended starting dose is 37 mg once a day, taken with food at approximately the same time of the day. Depending on the patient's response and the judgement of the treating doctor, the dose can be increased up to a maximum dose of 148 mg once a day. Lower doses should be used in patients with moderately or severely reduced kidney or liver function and in patients taking certain other medicines that may affect the levels of Latuda in the blood.

For further information, see the package leaflet.

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How does Latuda work?

The active substance in Latuda, lurasidone, is an antipsychotic medicine. It attaches to and affects several different receptors for neurotransmitters on the surface of nerve cells in the brain. Neurotransmitters are chemicals that allow nerve cells to communicate with each other.

Lurasidone acts mainly by blocking the receptors for the neurotransmitters dopamine, 5-hydroxytryptamine (also called serotonin) and noradrenaline. Since dopamine, 5-hydroxytryptamine and noradrenaline play a role in schizophrenia, by blocking their receptors lurasidone helps to normalise the activity of the brain, reducing symptoms.

What benefits of Latuda have been shown in studies?

Latuda has been investigated in six main studies. Three short-term studies compared Latuda with placebo (a dummy treatment) over six weeks in a total of 1,466 patients. The main measure of effectiveness was the change in the patient's symptoms, measured using a standard scale for schizophrenia called 'positive and negative syndrome scale' (PANSS). In these studies, different doses of Latuda were shown to be more effective than placebo, lowering the PANSS score by up to 16 points more than placebo; however, this effect was not consistently demonstrated for each dose and it was not possible to observe a consistent dose-response relationship. Further analyses of the results were carried out by the company, which supported the short-term benefits of treatment with Latuda.

One of the short-term studies was continued to 12 months (extension study) to look at the maintenance of the effect of Latuda in 292 patients, compared with quetiapine; two other studies, involving 914 patients, looked at the long-term effects of Latuda compared with another schizophrenia medicine, risperidone, or placebo, respectively. In these long-term studies, the effectiveness of Latuda was measured by the percentage of patients who relapsed and had symptoms of schizophrenia coming back during treatment. In the extension study, 21% of patients treated with Latuda had a relapse within one year, compared with 27% of patients treated with quetiapine, showing that Latuda was at least as effective as quetiapine. Latuda was not shown to be as effective as risperidone in the second study, although the available data supported a long-term benefit. The last study showed that 30% of patients treated with Latuda relapsed within one year, compared with 41% of patients treated with placebo.

What are the risks associated with Latuda?

The most common side effects with Latuda (which may affect more than 1 in 10 people) are akathisia (a constant urge to move) and somnolence (sleepiness). For the full list of all side effects reported with Latuda, see the package leaflet.

Latuda must not be used together with medicines known as 'strong CYP3A4 inhibitors' or 'strong CYP3A4 inducers', which may affect the levels of lurasidone in the blood. For the full list of restrictions, see the package leaflet.

Why is Latuda approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Latuda's benefits are greater than its risks and recommended that it be approved for use in the EU. While both short- and long-term effectiveness of Latuda have been sufficiently demonstrated, the CHMP noted that in the short-term studies its effectiveness was found to be moderate. Regarding safety, the side effects of Latuda were considered similar to those of other medicines of the same type, but it seemed to have

fewer effects on body metabolism (such as effects on blood levels of sugar and fat, and body weight) and might have less effect on the activity of the heart than some other available treatments.

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

A risk management plan has been developed to ensure that Latuda is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Latuda, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Latuda

The European Commission granted a marketing authorisation valid throughout the European Union for Latuda on 21 March 2014.

The full EPAR and risk management plan summary for Latuda 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 Latuda, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2014.