EMA/464462/2020
EMEA/H/C/002713

Latuda (*lurasidone*)

An overview of Latuda and why it is authorised in the EU

What is Latuda and what is it used for?

Latuda is a medicine that is used to treat patients from 13 years of age with schizophrenia, a mental illness with symptoms that include disorganised thinking and speech, hallucinations (hearing or seeing things that are not there), suspiciousness and delusions (mistaken beliefs).

Latuda contains the active substance lurasidone.

How is Latuda used?

Latuda can only be obtained with a prescription and in patients aged under 18 years it should be prescribed by an expert on mental illness in children. Latuda is available as tablets to take by mouth.

The recommended starting dose is 37 mg once a day, taken with food at around the same time each day. The doctor will then adjust the dose according to how well the condition is being controlled, up to a maximum dose of 148 mg once a day in adults and 74 mg once a day in younger patients.

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

How does Latuda work?

The active substance in Latuda, lurasidone, is an antipsychotic medicine. It works at several different receptors (targets) for neurotransmitters on 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 these neurotransmitters 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 6 weeks in a total of 1,466 adults. The main measure of effectiveness was the change in symptoms, measured using a standard scale for schizophrenia called

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

'positive and negative syndrome scale' (PANSS). In these studies, Latuda was found to be more effective than placebo, lowering the PANSS score by up to 16 points more than placebo; however, this effect was not consistent for each dose studied and it was not possible to see a consistent pattern of greater improvement with higher doses. Further analyses of the results by the company supported the likelihood of short-term benefits of treatment with Latuda.

One of the short-term studies was continued to 12 months to look at the effect of continuing use of Latuda in 292 adults, compared with the medicine quetiapine; two other studies, involving 914 adults, looked at the long-term effects of Latuda compared with another schizophrenia medicine, risperidone, or with placebo. In these long-term studies, effectiveness was measured in terms of the percentage of patients whose condition worsened, and whose symptoms came back during treatment. In the extension study, Latuda was at least as effective as quetiapine, with the condition worsening in 21% of patients treated with Latuda within 1 year, compared with 27% of patients treated with quetiapine. Latuda was not found to be as effective as risperidone in the second study but the available data supported a long-term benefit. The last study showed that the condition worsened in 30% of patients treated with Latuda within one year, compared with 41% of patients receiving placebo.

A further study involved 326 patients aged 13 to 17 years with schizophrenia whose symptoms had worsened markedly in the previous 2 months. After 6 weeks, PANSS scores improved by over 18 points in patients taking Latuda compared with an improvement of 10.5 points in those receiving placebo. Continuing use of Latuda for up to 2 years led to further improvement in PANSS scores.

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 sleepiness.

Latuda must not be used together with medicines considered to be 'strong CYP3A4 inhibitors' or 'strong CYP3A4 inducers', which may affect the levels of lurasidone in the blood.

For the full list of side effects and restrictions of Latuda, see the package leaflet.

Why is Latuda authorised in the EU?

Studies have found Latuda to be effective for treating schizophrenia in patients aged from 13 years in both the short-term and long-term, but its effectiveness was moderate in short-term studies. The European Medicines Agency noted that treatment options for adolescents with schizophrenia are limited. The side effects of Latuda were 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.

The Agency therefore decided that Latuda's benefits are greater than its risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Latuda have been included in the summary of product characteristics and the package leaflet.

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

Other information about Latuda

Latuda received a marketing authorisation valid throughout the EU on 21 March 2014.

Further information on Latuda can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/latuda.

This overview was last updated in 08-2020.