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EPAR summary for the public

Brintellix

vortioxetine

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

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

What is Brintellix and what is it used for?

Brintellix is an antidepressant medicine containing the active substance vortioxetine. It is used to treat major depression in adults. Major depression is a condition in which patients have mood disturbances that interfere with their everyday life. Symptoms often include deep sadness, feelings of worthlessness, loss of interest in favourite activities, sleep disturbances, a feeling of being slowed down, feelings of anxiety and changes in weight.

How is Brintellix used?

Brintellix can only be obtained with a prescription and is available as tablets (5, 10, 15 and 20 mg) and oral drops (20 mg/ml). The usual dose is 10 mg once a day. Patients 65 years of age and over should be started on a lower dose of 5 mg daily. Lower doses may also be needed in patients taking certain medicines that reduce the breakdown of vortioxetine in the body and conversely higher doses may be considered in those taking medicines that increase the breakdown of vortioxetine. Treatment with Brintellix should continue for at least 6 months after the depressive symptoms have resolved.

For further information, see the package leaflet.

How does Brintellix work?

The active substance in Brintellix, vortioxetine, is an antidepressant. It acts on different receptors for serotonin in the brain, blocking the action of some receptors and having some stimulant action on others. In addition, vortioxetine blocks the action of the serotonin transporter, which is responsible for

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clearing serotonin from its sites of activity in the brain, thus increasing the activity of serotonin. Serotonin is a neurotransmitter, a chemical that transmits signals between nerve cells. Because serotonin is involved in the control of mood, and can regulate the actions of other neurotransmitters that may be involved in depression and anxiety, these actions of vortioxetine are thought to result in its effect in improving depression.

What benefits of Brintellix have been shown in studies?

Brintellix has been studied in 12 main short-term studies involving more than 6,700 patients with major depression (including one study in patients aged 65 and over), in which it was compared with placebo (a dummy treatment) for 6 or 8 weeks. The main measure of effectiveness in each study was the change in a standard score for symptoms of depression; the studies showed that doses of Brintellix ranging from 5 to 20 mg were generally more effective than placebo in improving depression and resulted in a clinically relevant decrease of the depression scores. Supportive data from 52-week extensions of several of these studies suggested that the improvements that were seen were maintained longer-term.

In addition, the company presented results from two other main studies. In a 12-week comparison of Brintellix with another antidepressant, agomelatine, Brintellix was more effective than agomelatine in improving the symptom score. A 24-week study comparing the effect of Brintellix with placebo in preventing relapses of depression found that the proportion of patients given Brintellix who relapsed during the study was 13%, compared with 26% in the placebo group.

What are the risks associated with Brintellix?

The most common side effect with Brintellix, seen in more than 1 in 10 people is nausea (feeling sick). Side effects were usually mild or moderate, short-lasting and occurred in the first two weeks of treatment. Effects on the gut such as nausea are more common in women than in men. Brintellix must be used with care and sometimes in adjusted doses in patients taking certain other medicines; it must not be used in patients also taking medicines known as nonselective monoamine oxidase inhibitors (MAOIs) or selective monoamine oxidase A (MAO-A) inhibitors. For the full list of all side effects and restrictions, see the package leaflet.

Why is Brintellix approved?

The Agency’s Committee for Medicinal Products for Human Use (CHMP) decided that Brintellix’s benefits are greater than its risks and recommended that it be approved for use in the EU. Studies have shown a clinically relevant improvement in major depressive episodes, and the types of side effects seen were similar to those with other antidepressants that act through serotonin. Although there was limited information about the use of doses above 10 mg daily in the elderly this was addressed in the product information.

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

A risk management plan has been developed to ensure that Brintellix 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 Brintellix, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Brintellix

The European Commission granted a marketing authorisation valid throughout the European Union for Brintellix on 18 December 2013.

The full EPAR for Brintellix 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 Brintellix, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2014.