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EPAR summary for the public

Aripiprazole Zentiva

aripiprazole

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

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

What is Aripiprazole Zentiva and what is it used for?

Aripiprazole Zentiva is used in patients with the following mental illnesses:

- schizophrenia, a mental illness with a number of symptoms, including disorganised thinking and speech, hallucinations (hearing or seeing things that are not there), suspiciousness and delusions (false beliefs). Aripiprazole Zentiva is used in patients aged 15 years or over;
- bipolar I disorder, a mental illness in which patients have manic episodes (periods of abnormally high mood), alternating with periods of normal mood. They may also have episodes of depression. Aripiprazole Zentiva is used in adults to treat moderate to severe manic episodes and to prevent new manic episodes in adults who have responded to the medicine in the past. Aripiprazole Zentiva is also used for up to 12 weeks to treat moderate to severe manic episodes in patients aged 13 years or over.

Aripiprazole Zentiva contains the active substance aripiprazole and is a 'generic medicine'. This means that Aripiprazole Zentiva is similar to a 'reference medicine' already authorised in the European Union (EU) called Abilify. For more information on generic medicines, see the question-and-answer document here.

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How is Aripiprazole Zentiva used?

Aripiprazole Zentiva is available as tablets (5, 10, 15 and 30 mg) and orodispersible tablets (tablets that dissolve in the mouth; 10, 15 and 30 mg). It can only be obtained with a prescription.

For schizophrenia, the recommended starting dose is 10 or 15 mg by mouth per day in adults, followed by a 'maintenance' dose of 15 mg once a day. In patients aged between 15 and 17 years, the starting dose is 2 mg a day (using an aripiprazole product available in liquid form), which is gradually increased to the recommended dose of 10 mg once a day.

For treating manic episodes in bipolar disorder, the recommended starting dose in adults is 15 mg by mouth once a day, either on its own or in combination with other medicines. To prevent manic episodes in adults, the same dose should be continued.

For treating manic episodes in patients aged between 13 and 17 years, the starting dose is 2 mg a day (using an aripiprazole product available in liquid form), which is gradually increased to the recommended dose of 10 mg once a day. Treatment must not last longer than 12 weeks.

The dose should be adjusted in patients who are taking other medicines that affect the way Aripiprazole Zentiva is broken down in the body. For further information, see the Summary of Product Characteristics (also part of the EPAR).

The orodispersible tablets can be used in patients who have difficulty swallowing tablets.

How does Aripiprazole Zentiva work?

The active substance in Aripiprazole Zentiva, aripiprazole, is an antipsychotic medicine. 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. Aripiprazole is thought to act mainly by being a 'partial agonist' for the receptors for the neurotransmitters dopamine and 5-hydroxytryptamine (also called serotonin). This means that aripiprazole acts like dopamine and 5-hydroxytryptamine by activating these receptors, but less strongly than the neurotransmitters. Since dopamine and 5-hydroxytryptamine are involved in schizophrenia and bipolar disorder, aripiprazole helps to normalise the activity of the brain, reducing psychotic or manic symptoms and preventing them from returning.

How has Aripiprazole Zentiva been studied?

Because Aripiprazole Zentiva is a generic medicine, studies in people have been limited to tests to determine that it is bioequivalent to the reference medicine, Abilify. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Aripiprazole Zentiva?

Because Aripiprazole Zentiva 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 Aripiprazole Zentiva approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Aripiprazole Zentiva has been shown to have comparable quality and to be

bioequivalent to Abilify. Therefore, the CHMP's view was that, as for Abilify, the benefit outweighs the identified risk. The Committee recommended that Aripiprazole Zentiva be approved for use in the EU.

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

A risk management plan has been developed to ensure that Aripiprazole Zentiva 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 Aripiprazole Zentiva, 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.

In addition, the company that markets Aripiprazole Zentiva will provide educational materials to be supplied to patients or their caregivers and to doctors to explain the safe use of the medicine in patients between 13 and 17 years.

Other information about Aripiprazole Zentiva

The European Commission granted a marketing authorisation valid throughout the European Union for Aripiprazole Zentiva on 25 June 2015.

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

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 06-2015.