EMA/435672/2015
EMEA/H/C/004008

EPAR summary for the public

Aripiprazole Sandoz

aripiprazole

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

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

What is Aripiprazole Sandoz and what is it used for?

Aripiprazole Sandoz 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 Sandoz 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 Sandoz is used in adults to treat moderate to severe manic episodes and to prevent new manic episodes in adults whose illness has improved with the medicine in the past. Aripiprazole Sandoz is also used for up to 12 weeks to treat moderate to severe manic episodes in patients aged 13 years or over.

Aripiprazole Sandoz contains the active substance aripiprazole and is a 'generic' and a 'hybrid' medicine. This means that it is similar to a 'reference medicine', but it contains aripiprazole at a new strength in addition to existing strengths: while the reference medicine, Abilify, is available as 5, 10, 15 and 30 mg, Aripiprazole Sandoz is also available as 20 mg tablets. For more information on generic and hybrid medicines, see the question-and-answer document here.

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How is Aripiprazole Sandoz used?

Aripiprazole Sandoz is available as tablets and 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 Sandoz is broken down in the body. For further information, see the summary of product characteristics (also part of the EPAR).

How does Aripiprazole Sandoz work?

The active substance in Aripiprazole Sandoz, aripiprazole, is an antipsychotic medicine. Its exact mechanism of action is unknown, but it attaches to several different receptors on nerve cells in the brain. This disrupts signals transmitted between brain nerve cells by 'neurotransmitters', chemicals that allow nerve cells to communicate with each other. Aripiprazole is thought to act mainly by being a 'partial agonist' at 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. In this way, aripiprazole helps to change the activity of the nerve cells which are thought to give rise to psychotic or manic symptoms and preventing them from returning.

How has Aripiprazole Sandoz been studied?

The company provided data from the published literature on aripiprazole.

The company carried out 'bioequivalence' studies to show that Aripiprazole Sandoz 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 Sandoz?

Because Aripiprazole Sandoz is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Aripiprazole Sandoz approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Aripiprazole Sandoz 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 Sandoz be approved for use in the EU.

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

A risk management plan has been developed to ensure that Aripiprazole Sandoz 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 Sandoz, 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, when used for patients aged 13 years or older with moderate to severe manic episodes in bipolar I disorder, the company that markets Aripiprazole Sandoz will provide educational materials to be supplied to patients or their caregivers and to doctors to explain the safe use of the medicine in these patients.

Other information about Aripiprazole Sandoz

The European Commission granted a marketing authorisation valid throughout the European Union for Aripiprazole Sandoz on 20 August 2015.

The full EPAR and risk management plan summary for Aripiprazole Sandoz 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 Sandoz, 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 08-2015.