Summary Public Assessment Report

Generics

ARIPSAN 5 mg, 10 mg and 15 mg tablets

(aripiprazole)

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Active substance: aripiprazole

This is a summary of the public assessment report (PAR) for ARIPSAN 5 mg, 10 mg and 15 mg tablets. It explains how this medicine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use ARIPSAN.

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

What is ARIPSAN and what is it used for?
ARIPSAN is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Abilify.

The product 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). ARIPSAN 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. ARIPSAN is used in adults to treat moderate to severe manic episodes. In adult patients who have responded to the medicine it can help to prevent new manic episodes. The product is also used for up to 12 weeks to treat moderate to severe manic episodes in patients aged 13 years or over.

How does this medicine work?
The active substance in ARIPSAN, aripiprazole, is an antipsychotic medicine. Its exact mechanism of action is unknown, but it binds to several receptors on the surface of nerve cells in the brain. This binding reduces the effect of certain substances in the brain that are involved in schizophrenia and bipolar disorder. Psychotic or manic symptoms can thereby be reduced.

How is this medicine used?
The pharmaceutical form of ARIPSAN is a tablet and the route of administration is oral. The tablet should be taken with water, swallowed whole, and at the same time each day.

Aripiprazole is effective in a dose range of 10 mg to 30 mg per day. The maximum daily dose should not exceed 30 mg.

The medicine can only be obtained with a prescription.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

How has this medicine been studied?
Because ARIPSAN is a generic medicine, studies in patients 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 possible side effects of this medicine?
Because ARIPSAN is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be bioequivalent to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Abilify, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine 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 ARIPSAN, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

In addition, the company that markets ARIPSAN 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 this medicine
In the Netherlands, the marketing authorisation for ARIPSAN 5 mg, 10 mg en 15 mg tablets was granted on 8 March 2015.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human. For more information about treatment with ARIPSAN, read the package leaflet (http://mri.medagencies.org/download/NL_H_3244_001_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in August 2016.