

Summary Public Assessment Report

Generics

**Aripiprazole “Orion”
Aripiprazole**

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Aripiprazole “Orion”

Aripiprazole, tablets 5 mg, 10 mg, 15 mg and 30 mg

This is a summary of the public assessment report (PAR) for Aripiprazole “Orion”. It explains how Aripiprazole “Orion” 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 Aripiprazole “Orion”.

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

What is Aripiprazole “Orion” and what is it used for?

Aripiprazole “Orion” is a ‘generic medicine’. This means that Aripiprazole “Orion” is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Abilify.

Aripiprazole “Orion” can be used by adults and adolescents aged 15 years and older who suffer from a disease (schizophrenia) characterized by symptoms such as hearing, seeing or sensing things which are not there, suspiciousness, mistaken beliefs, incoherent speech and behavior and emotional flatness. People with this condition may also feel depressed, guilty, anxious or tense.

Aripiprazole “Orion” is also used to treat adults and adolescents aged 13 years and older who suffer from a condition (bipolar I disorder) with symptoms such as feeling “high”, having excessive amounts of energy, needing much less sleep than usual, talking very quickly with racing ideas and sometimes severe irritability. In adults it also prevents this condition from returning in patients who have responded to the treatment with Aripiprazole “Orion”.

How does Aripiprazole “Orion” work?

Aripiprazole “Orion” contains the active substance aripiprazole and belongs to a group of medicines called antipsychotics. It works by helping to restore the balance of certain natural chemicals in the brain (neurotransmitters).

How is Aripiprazole “Orion” used?

The pharmaceutical form of Aripiprazole “Orion” is tablets and the route of administration is oral.

Use in adults

The recommended dose for adults is 15 mg once a day. However, the doctor may prescribe a lower or higher dose to a maximum of 30 mg once a day.

Use in children and adolescents

Aripiprazole treatment may be started at a low dose with the oral solution (liquid) form. The dose may be gradually increased to the recommended dose for adolescents of 10 mg once a day. However, the doctor may prescribe a lower or higher dose to a maximum of 30 mg once a day.

Aripiprazole “Orion” tablets should be taken at the same time each day.

It does not matter whether it is taken with or without food. The tablet should be taken with water and swallowed whole.

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

The medicine can only be obtained with a prescription.

What benefits of Aripiprazole “Orion” have been shown in studies?

Because Aripiprazole “Orion” 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 Aripiprazole “Orion”?

Because Aripiprazole “Orion” 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 restrictions, see the package leaflet.

Why is Aripiprazole “Orion” approved?

It was concluded that, in accordance with EU requirements, Aripiprazole “Orion” has been shown to have comparable quality and to be bioequivalent/be comparable to Abilify. Therefore, the member states involved in the procedure concluded 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 Aripiprazole “Orion”?

A risk management plan has been developed to ensure that Aripiprazole “Orion” 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 “Orion”, 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.

Educational materials for both health care providers and patients/caregivers are required to be distributed to the healthcare providers at the time of marketing the product with the aim of clearly highlighting the need to give careful consideration to the indicated age range, dose, and duration of treatment before prescribing aripiprazole to a paediatric patient with bipolar I type disorder.

Other information about Aripiprazole “Orion”

The marketing authorisation for Aripiprazole “Orion” was granted on 3 June 2015.

The full PAR and the package leaflet for Aripiprazole “Orion” can be found on the website <http://mri.medagencies.org/Human/>. For more information about treatment with Aripiprazole “Orion”, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 10-2015.