Summary Public Assessment Report

Generics

Preheftari
Aripiprazole

DK/H/2422/001-004/DC

6 November 2015

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

This is a summary of the public assessment report (PAR) for Preheftari. It explains how Preheftari 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 Preheftari.

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

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

Preheftari 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.

Preheftariis 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 Preheftari.

How does Preheftari work?
Preheftaricontains 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 Preheftari used?
The pharmaceutical form of Preheftari 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.

Preheftaritablets 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 Preheftari have been shown in studies?
Because Preheftari 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 Preheftari?
Because Preheftari 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 Preheftari approved?
It was concluded that, in accordance with EU requirements, Preheftari 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 Preheftari?
A risk management plan has been developed to ensure that Preheftari 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 Preheftari, 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 Preheftari
The marketing authorisation for Preheftari was granted on 15 September 2015.

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

This summary was last updated in 11-2015.