EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 April 2015
EMA/CHMP/227409/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion 1 (initial authorisation)

Aripiprazole Pharmathen

aripiprazole

On 23 April 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Aripiprazole Pharmathen, intended for the treatment of schizophrenia as well as treatment and prevention of manic episodes in bipolar I disorder. The applicant for this medicinal product is Pharmathen S.A.

Aripiprazole Pharmathen will be available as 5 mg, 10 mg, 15 mg and 30 mg tablets.

The active substance of Aripiprazole Pharmathen is aripiprazole, an antipsychotic medicine (ATC code: N05AX12). Its exact mechanism of action is unknown, but it acts as a partial agonist, attaching to several different receptors for the neurotransmitters dopamine and serotonin on the surface of nerve cells in the brain. This action disrupts signals transmitted between brain cells by these neurotransmitters, and thereby helps to normalise the activity of the brain, reducing psychotic or manic symptoms and preventing them from returning.

Aripiprazole Pharmathen is a generic of Abilify, which has been authorised in the EU since June 2004. Studies have demonstrated the satisfactory quality of Aripiprazole Pharmathen, and its bioequivalence to the reference product Abilify. A question and answer document on generic medicines can be found here.

The full indication is:

“Aripiprazole Pharmathen is indicated for the treatment of schizophrenia in adults and in adolescents aged 15 years and older.

Aripiprazole Pharmathen is indicated for the treatment of moderate to severe manic episodes in Bipolar I Disorder and for the prevention of a new manic episode in adults who experienced predominantly manic episodes and whose manic episodes responded to aripiprazole treatment (see section 5.1).

Aripiprazole Pharmathen is indicated for the treatment up to 12 weeks of moderate to severe manic episodes in Bipolar I Disorder in adolescents aged 13 years and older (see section 5.1).”

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.