17 October 2016

Important Safety Change to Abilify tablet and Abilify Maintena Product Information

Otsuka Australia and Lundbeck Australia draw your attention to changes to the Abilify® (aripiprazole) and Abilify Maintena® (aripiprazole prolonged-release injection) Product Information. The following has been added to the Precautions section of the Product Information for both products:

**Pathological gambling and impulse-control disorders**

Patients can experience increased urges, particularly for gambling, and the inability to control these urges while taking aripiprazole. Other urges reported include: increased sexual urges, compulsive spending, binge or compulsive eating, and other impulsive and compulsive behaviours. It is important for prescribers to ask patients or their caregivers specifically about the development of new or increased gambling urges, sexual urges, compulsive spending, binge or compulsive eating, or other urges while being treated with aripiprazole. It should be noted that impulse-control symptoms can be associated with the underlying disorder; however, in some cases urges were reported to have stopped when the dose was reduced or the medication was discontinued. Impulse control disorders may result in harm to the patient and others if not recognized. Consider dose reduction or stopping the medication if a patient develops such urges while taking aripiprazole.

In addition, hypersexuality, pathological gambling, impulse-control disorders, obsessive-compulsive disorder and eating disorder have been added to the post-market adverse drug reactions section of the Product Information of both products.

Please call Otsuka Australia for enquiries related to Abilify® tablets or to obtain the Product Information leaflet on 1800 059 606.

Please call Lundbeck Australia for enquiries related to Abilify Maintena® prolonged-release injection or to obtain the Product Information leaflet on 1300 721 277.

Any adverse events in patients taking Abilify® tablets should be reported to OAPmedical@au.otsuka.com and those with Abilify Maintena® should be reported to SafetyLuAustralia@lundbeck.com
Suspected adverse events associated with the use of health products can also be reported to the Therapeutic Goods Administration (TGA) as follows:


**by post to:** Therapeutic Goods Administration, PO Box 100, Woden, ACT 2606, Australia (please include the type of report in the address block)

**via email:** adr.reports@tga.gov.au

**via fax:** +61 2 6232 8392.

Yours Faithfully,

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