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4th August, 2014

**CONCERTA® (METHYLPHENIDATE HYDROCHLORIDE): ADDITIONAL PRECAUTION – PRIAPISM**

Dear Healthcare Professional,

Janssen-Cilag New Zealand would like to inform you of the following addition to the PRECAUTIONS section of the Data Sheet for CONCERTA® (methylphenidate hydrochloride):

***Priapism***

*Prolonged and painful erections requiring immediate medical attention (sometimes including surgical intervention), have been reported with methylphenidate products, including CONCERTA, in both paediatric and adult patients. Priapism can develop after some time on methylphenidate, often subsequent to an increase in dose. Priapism has also appeared during a period of methylphenidate withdrawal (drug holidays or during discontinuation). Patients who develop abnormally sustained erections or frequent and painful erections should seek immediate medical attention.*

In October 2013, the US FDA requested class labeling changes to be implemented following evidence of an association between priapism and the use of stimulants used in the treatment of ADHD.

Based on this safety signal, the company conducted an analysis of available information. A cumulative review identified some cases of priapism reported worldwide with the use of methylphenidate, of which 2 cases reported a positive dechallenge and rechallenge providing sufficient evidence to consider priapism related to the use of CONCERTA®. The estimated reporting frequency of priapism and CONCERTA® is considered very rare at approximately 25 per 12,371,561 person-years based on spontaneous reporting rates. Therefore, the Adverse Events section of the Data Sheet has been updated to include priapism.

Please review the full Data Sheet for CONCERTA® which is available from http://www.medsafe.govt.nz/. For further information please contact Janssen Medical Information on 0800 800 806 or medinfo@janau.jnj.com.

Adverse Event Reporting

Janssen is committed to ensuring that our products are used safely and effectively. We have a responsibility to report and follow up on all adverse events whether or not there is a definite causal relationship. In order to monitor the safety of our products, we encourage prescribers and other healthcare professionals to report adverse events for Janssen products by calling Medical Information or Drug Safety on 0800 800 806, by fax to +612 9888 9817, or via email to medinfo@janau.jnj.com. Reports can also be made to the Centre for Adverse Reactions Monitoring (CARM) in Dunedin by calling 03 479 7247, by fax 03 479 7150, or via email to carmnz@otago.ac.nz.

Yours sincerely,

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