JANSSEN-CILAG Ltd

IMPORTANT SAFETY INFORMATION

RISPERDAL® (Risperidone) in elderly patients with dementia

Information on Cerebrovascular Adverse Events

16th April 2004

Dear Healthcare Professional,

Following discussions with the Irish Medicines Board (IMB), Janssen-Cilag Ltd would like to inform you of important new, safety information regarding RISPERDAL® (risperidone) and its use in elderly patients with dementia. This information is based on data from placebo-controlled trials which identified a three fold increase in the incidence of cerebrovascular adverse events (CVAE's) in elderly patients with dementia treated with risperidone, compared with placebo. Following evaluation of the data, the indication for treatment of behavioural disturbances in patients with dementia has been revised to restrict use, as follows:

> **Risperdal is indicated for the treatment of severe behavioural disturbances in patients with dementia in whom symptoms such as aggressiveness (verbal outbursts, physical violence), activity disturbances (agitation, wandering) or psychotic symptoms are prominent and lead to patient suffering, disability, potential danger or self harm.**
>
> **Such patients should be closely monitored and Risperdal continued only if the benefits of treatment are considered to outweigh the risks for the individual patient.**

In addition, the following information has been added to the Special Warnings and Special Precautions for Use section of the Summary of Product Characteristics (SmPC):

> **Data from randomized clinical trials conducted in elderly (>65 years) patients with dementia indicate that there is an approximately 3-fold increased risk of Cerebrovascular adverse events (including Cerebrovascular accidents, some of which were fatal and transient ischaemic attacks) in patients treated with risperidone, compared with placebo. Cerebrovascular adverse events (CVAE's) occurred in 3.3% (33/989) of patients treated with risperidone and 1.2% (8/693) of patients treated with placebo.**

This update is based on data from 6 placebo-controlled trials conducted in elderly patients with dementia (n>1700).

These changes, together with additional advice on risk factors to be considered prior to treatment and recommendations for on-going patient monitoring, have been incorporated in the SmPC (sections 4.1, 4.2b, 4.4, 4.8). A revised version of the SmPC is attached for your information.

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All suspected adverse events should be reported to Janssen-Cilag Ltd and/or the IMB in the usual way.

Janssen-Cilag Ltd remains committed to providing you with the most current product information available for the management of your patients. For further information on the above or for additional medical information about RISPERDAL®, please call Janssen-Cilag Medical Information on 1800709122.

Sincerely,

Dr R Donnelly

Dr Robert Donnelly
Medical Director
Janssen-Cilag Ltd

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