

Important Product Information Restriction of the dementia indication for risperidone

This communication has also been posted on the Janssen Inc. website at www.janssen.ca and on the Health Canada website at www.healthycanadians.gc.ca

Date 02/18/2015

Audience

Health professionals working in the following settings: Geriatrics, Geriatric Psychiatry, Internal Medicine, Extended Care Facilities, Nursing Homes and Pharmacies.

Key messages

- The review of safety information related to antipsychotic drugs indicated a higher risk of cerebrovascular adverse events in patients with mixed and vascular dementia compared to those with dementia of the Alzheimer type.
- The indication for risperidone in dementia has been restricted to the short-term symptomatic management of aggression or psychotic symptoms in patients with **severe dementia of the Alzheimer type** unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others. The indication no longer includes the treatment of other types of dementia such as vascular and mixed types of dementia.
- Physicians are advised to assess the risks and benefits of the use of risperidone in elderly patients with **severe dementia of the Alzheimer type**, taking into account risk predictors for stroke or existing cardiovascular comorbidities in the individual patients.

What is the issue?

Janssen Inc., in consultation with Health Canada would like to inform healthcare professionals, caregivers and patients of important updates to the indication of risperidone for severe dementia. The decision to limit risperidone's indication to **severe dementia of the Alzheimer type** is based on a comprehensive evaluation of the safety information related to all antipsychotic drugs which indicated a higher risk of cerebrovascular adverse events in patients with the mixed or vascular dementia compared to those with dementia of the Alzheimer type.

Products affected

RISPERDAL® (risperidone tablets and oral solution)
RISPERDAL M-TAB® (risperidone orally disintegrating tablets)
All generic versions of risperidone oral formulations

Background information

Prior to this dementia indication update, risperidone was approved for use in severe dementia. The indication for risperidone in dementia has been limited to **Severe Dementia of the Alzheimer type— Symptomatic management of aggression and psychotic symptoms**. Elderly patients with dementia treated with antipsychotic drugs present an increased risk of death compared to placebo, mostly due to cardiovascular events and infections.

Information for consumers

Risperidone belongs to a group of medicines called antipsychotic drugs.

Risperidone may be used for short-term treatment to control aggression or psychotic symptoms (hallucinations or delusions) in **severe dementia of the Alzheimer type**. Dementia is a brain disease that decreases the ability to think and remember. Risperidone is no longer recommended for use in other types of dementia such as vascular and mixed types of dementia.

Patients and caregivers should contact their Healthcare Professional for further information and questions about risperidone therapy. Additional information about risperidone is also provided in the Part III: Consumer Information section of the RISPERDAL[®] Product Monograph (<http://www.janssen.ca/product/185>).

Information for health care professionals

Physicians are advised to assess the benefits and risks of the use of risperidone in elderly patients with **severe dementia of the Alzheimer type**, taking into account risk predictors for stroke or existing cardiovascular comorbidities in the individual patient.

Please refer to the RISPERDAL[®] Product Monograph for full prescribing information. The current RISPERDAL[®] Product Monograph can be found at the Janssen Canada Web site (<http://www.janssen.ca/product/185>) and Health Canada's Web page (<http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp>).

Action taken

The Product Monograph for RISPERDAL[®] (risperidone tablets and oral solution) and RISPERDAL M-TAB[®] (risperidone orally disintegrating tablets) has been updated with this new information.

Report health or safety concerns

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of serious or unexpected side effects in patients receiving risperidone should be reported to Janssen Inc. or Health Canada.

Drug Safety Department
Janssen Inc.
19 Green Belt Drive
Toronto, Ontario
M3C 1L9
Or call toll free at 1-866-825-7122
Or email to dsscan@joica.jnj.com

Or fax to 1-866-767-5865

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on [Adverse Reaction Reporting](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax

For other health product inquiries related to this communication, please contact Health Canada at:

Marketed Health Products Directorate
E-mail: mhpd_dpsc.public@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

For change of address, fax number or transmission difficulties regarding this notification please email info@ptm-health.com or fax 1-888-780-4268.

Should you have any questions or require additional information, please contact Janssen Inc. Medical Information Department at 1-800-567-3331 or 1-800-387-8781 from 8:30 a.m. to 4:30 p.m. Monday to Friday Eastern Standard Time (EST).

Sincerely,



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Vice President
Regulatory Affairs and Quality Management
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