

Advisory

May 26, 2006

For immediate release

New cautions regarding rare heart-related risks for all ADHD drugs

OTTAWA - Health Canada has revised the prescribing and patient information for all drugs used for the management of ADHD (Attention Deficit Hyperactivity Disorder) and advises Canadians not to use them if they have high blood pressure, heart disease or abnormalities, hardening of the arteries or an overactive thyroid gland.

The new prescribing and patient information applies to both adults and children.

Standardized labeling that identifies risk factors for rare heart-related side effects, and new recommendations to physicians have been added to the prescribing information for the following drugs, and for any products containing these drugs:

ADDERALL XR®	mixed salts amphetamine extended-release
ATTENADE™	dextromethylphenidate [approved by Health Canada, but the manufacturer has not marketed in Canada]
BIPHENTIN®	methylphenidate controlled release [approved by Health Canada, but the manufacturer has not marketed in Canada]
CONCERTA®	methylphenidate extended release
DEXEDRINE®	dextroamphetamine
RITALIN®	methylphenidate
RITALIN SR®	(methylphenidate extended release)
STRATTERA®	atomoxetine

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ADHD drugs are generally safe and provide benefits for Canadians and their treatment of ADHD when used as directed. Decisions about taking any of the drugs are best made in consultation with a physician.

Before using these drugs, patients should inform their doctor if they are involved in strenuous exercise or activities, are using other drugs for ADHD, have certain heart-related conditions or have a family history of sudden cardiac death. Health Canada stresses that patients should not stop taking ADHD medication without first consulting their doctors.

All ADHD drugs stimulate the heart and blood vessels (cardiovascular system). The effects are usually mild or moderate, but in some patients, this stimulation may – in rare cases – result in cardiac arrests, strokes or sudden death.

Patients taking ADHD drugs should consult with their physician if they have any questions or concerns.

Health Canada continues to monitor the safety of these drugs and Canadians will continue to be informed if new concerns arise. For more information, please see the Health Canada [letter to healthcare professionals](#) regarding this issue.

To report a suspected adverse reaction to ADHD drugs, please contact the Canadian Adverse Drug Reaction Monitoring Program (CADRMP) of Health Canada by one of the following methods:

Telephone: 866-234-2345 Facsimile: 866-678-6789

CADRMP

Marketed Health Products Directorate

Health Protection Building, Tunney's Pasture, AL 0701C

Ottawa, ON

K1A 0K9

Email: cadrmpp@hc-sc.gc.ca

Consumers requiring more information about this advisory can contact Health Canada's public enquiries line at (613) 957-2991, or toll free at 1-866-225-0709.

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Media Inquiries:

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1-866 225-0709