

Cobalt Pharmaceuticals Inc.
Genpharm
Laboratoire Riva Inc.
Novopharm Limited
Pharmascience Inc.
ratiopharm
Sandoz Canada Inc.
Wyeth Canada

PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
VENLAFAXINE XR

October 23, 2008

SUBJECT: Safety Information Regarding Overdosage of Venlafaxine HCl Extended-Release Capsules

Health Canada, and the manufacturers of venlafaxine extended-release (XR) capsules wish to advise Canadians that the prescribing information for venlafaxine XR is being updated to include safety information about the risks of overdose.

Venlafaxine is in a class of medicines called serotonin and norepinephrine reuptake inhibitors (SNRIs), and is used to treat depression, generalized anxiety disorder (GAD), social anxiety disorder (or social phobia) and panic disorder. Venlafaxine XR is sold in Canada under several brand names, including Effexor XR, Co Venlafaxine XR, Gen-Venlafaxine XR, Riva-Venlafaxine XR, Novo Venlafaxine XR, PMS- Venlafaxine XR, Ratio-Venlafaxine XR, Sandoz Venlafaxine XR.

We are taking this opportunity to remind Canadians that:

- Patients experiencing depression are at increased risk of suicidal or self-harming thoughts or behaviours.
- Some patients taking antidepressants may feel worse instead of better, particularly within the first few weeks of treatment or when doses are adjusted. For example, they may experience unusual feelings of agitation, hostility or anxiety, or have impulsive or disturbing thoughts that could involve self-harm or harm to others.
- If you, or a family member or a friend are depressed or taking antidepressants, you should seek medical attention immediately if there are signs of worsening depression, especially thoughts or talk about self-harm or suicide.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of overdose or other serious or unexpected adverse reactions in patients receiving venlafaxine XR should be reported to the manufacturer or Health Canada at the following addresses:

Cobalt Pharmaceuticals Inc.

6500 Kitimat Road
Mississauga, Ontario L5N 2B8
Tel: 1-866-254-6111
Fax: 905-542-0478
www.cobaltpharma.com

Genpharm

Drug Safety
85 Advance Road
Etobicoke, Ontario M8Z 2S6
Tel: 1-800-668-3174 ext. 152
Fax: 416-236-4363
Email: pharmacovigilance@genpharm.ca

Laboratoire Riva Inc.

660 Boul. Industriel
Blainville, Quebec J7C 3V4
Tel: 1-800-363-7988
Fax: 450-434-2500

Novopharm Limited

Pharmacovigilance and Drug Safety
30 Novopharm Court
Toronto, Ontario M1B 2K9
Tel: 416-291-8888 ext. 5005
Fax: 416-335-4472
PhV@Novopharm.com

Pharmascience Inc.

6111 Royalmount Avenue, Suite 100
Montreal, Quebec H4P 2T4
Tel: 1-800-363-8805
Fax: 514-342-7764

ratiopharm

17800 Lapointe
Mirabel, Quebec J7J 1P3
Tel: 1-800-337-2584
Fax: 1-800-313-7673
www.ratiopharm.ca

Sandoz Canada Inc.

145, Jules-Leger
Boucherville, Quebec J4B 7K8
Tel: 1-800-343-8839 ext. 4636
Fax: 1-888-243-6221

Wyeth Canada

Medical Information and Pharmacovigilance
50 Minthorn Boulevard
Markham, Ontario L3T 7Y2
Tel: 1-800-461-8844
Fax: 905-470-4385

Any suspected adverse reaction can also be reported to:

Canada Vigilance Program
Marketed Health Products Directorate

HEALTH CANADA

Address Locator: 0701C

Ottawa, Ontario, K1A 0K9

Tel: 613-957-0337 or Fax: 613-957-0335

To report an Adverse Reaction, consumers and health professionals may call toll free:

Tel: 866-234-2345

Fax: 866-678-6789

CanadaVigilance@hc-sc.gc.ca

The [AR Reporting Form](#) and the [AR Guidelines](#) can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php

http://hc-sc.gc.ca/dhp-mps/pubs/medeff/guide/2008-ar-ei_guide-ldir/index-eng.php

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

Marketed Health Products Directorate (MHPD)

E-mail: MHPD_DPSC@hc-sc.gc.ca

Tel: (613) 954-6522

Fax: (613) 952-7738

Authorized by:

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