



Lundbeck LLC

August 28, 2015

Re: Updated Product Monograph for FRISIUM® (clobazam)

Dear Healthcare Professional,

This letter, initiated voluntarily by Lundbeck LLC, is to inform you of the latest approval by Health Canada of the updated Product Monograph for FRISIUM (clobazam). FRISIUM is an antiepileptic indicated for adjunctive therapy in patients with epilepsy who are not adequately stabilized with their current anticonvulsant therapy.

There have been rare post-marketing case reports of serious skin reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), in clobazam-treated patients. In each of these reports, patients were receiving clobazam in addition to other medicines, including epilepsy medicines that are associated with serious skin reactions.

The revised Product Monograph for FRISIUM includes updated information under the following sections:

Warnings and Precautions

Adverse Reactions

Patient Medication Information

WARNINGS AND PRECAUTIONS

Skin - Serious skin reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported with FRISIUM in both children and adults during the postmarketing period. Patients should be closely monitored for signs or symptoms of SJS/TEN, especially during the first 8 weeks of treatment initiation or when re-introducing therapy. FRISIUM should be discontinued at the first sign of rash, unless the rash is clearly not drug-related. If signs or symptoms suggest SJS/TEN, use of this drug should not be resumed and alternative therapy should be considered.

ADVERSE REACTIONS

Skin and subcutaneous tissue disorders: Rash, urticaria, exanthema, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) (see WARNINGS AND PRECAUTIONS section)

Additional Important Information

Patients or caregivers should be instructed to inform their healthcare provider of any skin reactions that occur during treatment with FRISIUM. This includes skin peeling, itch, redness, and blisters of the lips, eyes, mouth, nasal passages or genitals. It is recommended that treatment should be discontinued at the first appearance of skin rash. (Please refer to PATIENT MEDICATION INFORMATION, for complete information).

Please refer to the full updated Canadian Product Monograph that can be found on the Health Canada Web page (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index_e.html) and on Lundbeck LLC's Web site (<http://www.lundbeck.com/us/products/products-beyond-the-us/americas/canada/frisium>).

Healthcare professionals should inform patients and their caregivers about the signs of these rare but serious skin reactions and that FRISIUM should be discontinued at the first appearance of skin rash. Cases of skin reactions or other serious or unexpected adverse reactions in patients receiving FRISIUM should be reported to Lundbeck or Health Canada.

Lundbeck Medical Information and Pharmacovigilance Service:

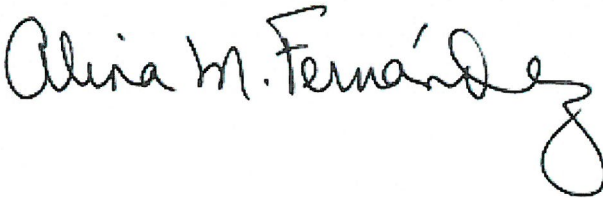
- Call toll-free at 1-866-880-4636; or
- By email: CanadaMedicalInformation@Lundbeck.com

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

- Call toll-free at 1-866-234-2345; or
- Visit MedEffect Canada's Web page on Adverse Reaction Reporting (<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.

Lundbeck LLC continues to ensure that up-to-date information concerning the use of FRISIUM (clobazam) is available to Canadian Healthcare Professionals.

Sincerely,



Alina M. Fernandez, MD, MPH, MBA
VP, Global Pharmacovigilance-US

[Click here](#) to continue to receive Product & Program Information, as well as other healthcare communications, by email from PTM/FORMEDIC.

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