

Public Communication - Health Canada Endorsed Important Safety Information on TECFIDERA™ (dimethyl fumarate)

biogen idec®

February 6, 2015

Subject: Risk of Rare Brain Condition Known as Progressive Multifocal Leukoencephalopathy (PML) with TECFIDERA™ (dimethyl fumarate)

Biogen Idec Canada Inc., in consultation with Health Canada, would like to inform you of important new safety information regarding the risk of a rare brain condition (PML) with TECFIDERA.

TECFIDERA is a medication to treat relapsing remitting multiple sclerosis (MS).

- A patient taking TECFIDERA died from a complication of a rare brain infection (PML). The patient had very low lymphocyte counts for over 3.5 years. Lymphocytes are important blood cells that help fight infections. Low lymphocyte counts are a known side effect of TECFIDERA and are associated with an increased risk of PML.
- The risk of PML is being added to the TECFIDERA Product Information document. This document is also being updated to recommend that lymphocytes be measured as part of the blood work done before and during treatment with TECFIDERA. If your lymphocyte counts stay very low for more than 6 months, your doctor may interrupt your TECFIDERA treatment and follow your lymphocyte counts until they return to normal.
- PML usually occurs in people with weakened immune systems. Some symptoms of PML are similar to those of MS and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes. If you develop any of these symptoms, you should seek medical attention.

A copy of this letter can be accessed on the [Health Canada Web site](#) and on the [Biogen Idec Canada Inc. Web site](#).

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of serious low lymphocyte counts or other serious or unexpected side effects in patients receiving TECFIDERA should be reported to Biogen Idec Canada Inc. or Health Canada.

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You can report any suspected side effect 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 \(http://www.hc-sc.gc.ca/dhp-mps/medeff/repodeclaration/index-eng.php\)](http://www.hc-sc.gc.ca/dhp-mps/medeff/repodeclaration/index-eng.php) for information on how to report online, by mail or by fax

For other health product inquiries related to this communication, 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

Sincerely,

Original signed by

Len Walt, M.D., MBA
Medical Director