Tysabri safety information updated in Canada

Biogen Idec Canada, in conjunction with Health Canada, has issued new safety information concerning progressive multifocal leukoencephalopathy (PML) associated with Tysabri (natalizumab). [1,2]

During the postmarketing period to date, there have been five confirmed cases of PML (one fatal) in patients receiving Tysabri monotherapy; four cases were reported in the EU and one in the US.[1] The cases highlight the importance of continued clinical vigilance and prompt discontinuation of Tysabri when PML is suspected, followed by appropriate evaluation including MRI and CSF testing for JC viral DNA. The Warnings and Precautions section, and the Consumer Information section of the labelling have been updated to include these reports of Tysabri-associated PML in the postmarketing monotherapy setting, and to provide additional clarification of the typical PML symptoms.

1. Biogen Idec. Updated safety information regarding progressive multifocal leukoencephalopathy (PML) associated with TYSABRI (Rm) (natalizumab). Internet Document : [2 pages], 13 Feb 2009. Available from: URL: http://www.hc-sc.gc.ca.
2. Biogen Idec. Reports of progressive multifocal leukoencephalopathy (PML) with TYSABRI (Rm) (natalizumab). Internet Document : [2 pages], 13 Feb 2009. Available from: URL: http://www.hc-sc.gc.ca.

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» **Editorial comment:** In 2005, Biogen Idec voluntarily suspended marketing of Tysabri after receiving one fatal and one possible report of PML in patients enrolled in a clinical trial who had been receiving the drug for MS for > 2 years [see Reactions 1041 p2; 809045831]. The following year, the US FDA approved the reintroduction of Tysabri in the US, based on review of clinical trial data, revised labelling and a risk management plan [see Reactions 1106 p3; 801069048]. Since then, details of three cases of Tysabri-linked PML in the postmarketing period have been published in Reactions [see Reactions 1214 p4; 801075330 and 1227 p3; 801075416].