

**MEDICAL UPDATE MEMO  
DECEMBER 16, 2003**

**HEALTH CANADA ADVISORY LETTER  
REGARDING INTERFERON TREATMENT**

**SUMMARY**

On December 4, 2003, Health Canada sent a letter to all Canadian health care professionals advising them of cases of serious hepatic (liver) injury reported in a small number of people who have received beta interferon treatment. Health care professionals are advised that liver function should be tested at the start of beta interferon therapy, every month for the first six months of therapy and at six month intervals thereafter. The Health Canada letter emphasizes that the occurrence of hepatic injury in people on beta interferon therapy is rare.

**DETAILS**

On December 4, 2003, Health Canada sent a letter to all Canadian health care professionals advising them of cases of serious hepatic (liver) injury reported in a small number of people who have received beta interferon treatment. Serious hepatic injury can include: autoimmune hepatitis, hepatitis, hepatic (liver) failure. A total of three cases of hepatic failure requiring liver transplantation have been reported world wide with beta interferon-products. One case occurred in Canada. The Health Canada letter reported that the Canadian case involved the simultaneous use of a non-MS drug known to have toxic effects on the liver and urged caution in prescribing drugs with documented liver toxicity to people who are also taking one of the beta interferons. The three beta interferon products are: Avonex (interferon beta-1a), Betaseron (interferon beta-1b) and Rebif (interferon beta-1a).

The Health Canada letter advises health care professionals that liver function testing should take place when beta interferon therapy is initiated to establish a baseline, then every month for the first six months and at six month intervals thereafter. The letter also advises that dose reduction or discontinuation of beta interferon therapy should be strongly considered if alanine aminotransferase (ALT) levels increase five times above the upper limit of normal. In addition, the Health Canada letter suggests that beta

interferon therapy should be initiated with caution in people with a history of significant liver disease, alcohol abuse and people with clinical evidence of active liver disease.

The Health Canada letter emphasizes that the occurrence of hepatic injury in people on beta inteferon therapy is rare. This is defined as a reporting rate of between 1/1,000 and 1/10,000 patient-years of exposure.

The signs and symptoms of hepatic injury include jaundice, wide-spread itching, nausea and vomiting, and easy bruising of the skin. People experiencing these signs and symptoms should immediately contact their physicians.

The Health Canada letters asks health care professionals to report any suspected adverse reactions in people receiving beta interferons to the relevant companies or to Health Canada directly. The contact information for each is:

AVONEX®  
Biogen Idec Canada Inc.  
Medical Services  
Tel: (905) 897-3234  
Fax: (905) 897-3222

BETASERON®  
Berlex Canada Inc.  
Tel: 1-800-361-0240  
Fax: (514)782-2243

REBIF®  
Serono Canada Inc.  
Tel: 1-888-737-6668  
Fax: (905) 825-3209

HEALTH CANADA  
Canadian Adverse Reaction  
Monitoring Program  
Marketed Health Products Directorate  
Tel: 1-866 234-2345  
Fax: 1-866-678-6789  
cadrmp@hc-sc.gc.ca

National Communications and Social Action Department  
National Research Department

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