

## **Rebif Adverse Reactions**

### **Interferon Beta-1a (Rebif) Associated Rarely With Severe Hepatic Injury**

On Dec. 23, the FDA approved revisions to the safety labeling for interferon beta-1a injection (Rebif, made by Serono, Inc.), warning of the risk of severe hepatic injury rarely associated with its use.

The FDA has received rare reports of liver injury, in some cases resulting in hepatic failure and necessitating transplantation, in patients receiving interferon beta-1a. Symptoms of liver dysfunction were observed from one to six months after initiation of therapy. The FDA notes that asymptomatic serum elevation of hepatic transaminases (particularly alanine aminotransferase (ALT; SGPT) is common with interferon therapy.

Treatment with interferon beta-1a should be discontinued in patients who develop jaundice and other signs of liver dysfunction due to the potential for rapid progression to liver failure.

Caution is recommended when initiating therapy in patients with active liver disease, alcohol abuse, elevated serum ALT levels (> 2.5 times the upper limit of normal [ULN]), or a history of significant liver disease.

Dose reduction is advised in patients with ALT levels more than five times the ULN. Dosing may gradually be increased once enzyme levels have normalized.

The potential for hepatic injury should be considered when using interferon beta-1a in combination with known hepatotoxic products or when adding new agents to the current regimen.

Interferon beta-1a is indicated for the reduction of the frequency of clinical exacerbations of multiple sclerosis and to delay the accumulation of physical disability in patients with relapsing forms of multiple sclerosis.