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Drug Safety and Availability - FDA warns about rare but serious risks of stroke and blood vessel wall tears with multiple sclerosis drug Lemtrada (alemtuzumab)

Center for Drug Evaluation and Research

3-4 minutes

[**11-29-2018**] The U.S. Food and Drug Administration (FDA) is warning that rare but serious cases of stroke and tears in the lining of arteries in the head and neck have occurred in patients with multiple sclerosis (MS) shortly after they received Lemtrada (alemtuzumab). These problems can lead to permanent disability and even death. As a result, we have added a new warning about these risks to the prescribing information in the drug label and to the patient Medication Guide. We have also added the risk of stroke to the existing *Boxed Warning*, FDA's most prominent warning.

Alemtuzumab is also approved under the brand name Campath, which was approved in May 2001 to treat a type of cancer called B-cell chronic lymphocytic leukemia (B-CLL). The Campath drug label will also be updated to include these risks in the *Adverse Reactions* section under *Postmarketing Experience*.

Patients or their caregivers should seek emergency treatment as soon as possible if the patient experiences signs or symptoms of a stroke or tears in the lining of the head and neck arteries, called arterial dissection, which can include:

- Sudden numbness or weakness in the face, arms, or legs, especially if it occurs on only one side of the body
- Sudden confusion, trouble speaking, or difficulty understanding speech
- Sudden trouble seeing in one or both eyes
- Sudden trouble with walking, dizziness, or loss of balance or coordination
- Sudden severe headache or neck pain

Most patients taking Lemtrada who developed stroke or tears in the artery linings, developed symptoms within 1 day of receiving Lemtrada. One patient reported symptoms that occurred 3 days after treatment.

Health care professionals should advise patients at every Lemtrada infusion to seek immediate emergency medical attention if they experience symptoms of ischemic or hemorrhagic stroke or cervicocephalic arterial dissection. The diagnosis is often complicated because early symptoms such as headache and neck pain are not specific. Promptly evaluate patients who complain of symptoms consistent with these conditions.

In the nearly five years since FDA approved Lemtrada in 2014 to treat relapsing forms of MS, we identified 13 worldwide cases of ischemic and hemorrhagic stroke or arterial dissection that occurred shortly after the patient received Lemtrada (see Data Summary). This number includes only reports submitted to FDA,* so additional cases we are unaware of may have occurred. Twelve of these cases reported symptoms within 1 day of receiving Lemtrada. As a result, we have added a new warning about this risk in the *Warnings and Precautions* section of the prescribing information in the drug label. We have also added the risk of stroke to the existing *Boxed Warning*, FDA's most prominent warning.

To help FDA track safety issues with medicines, we urge health care professionals to report side effects from Lemtrada or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

*The cases were reported to the FDA Adverse Event Reporting System (FAERS).