

Lemtrada[®] (alemtuzumab) – New warning

- On November 29, 2018, the [FDA announced](#) that a new warning about the rare but serious cases of stroke and tears in the lining of arteries in the head and neck occurring in patients taking [Lemtrada \(alemtuzumab\)](#) will be added to the Lemtrada drug label and patient Medication Guide. The risk of stroke will also be added to Lemtrada's *Boxed Warning*.
 - Lemtrada is indicated for the treatment of patients with relapsing forms of multiple sclerosis.
- Alemtuzumab is also approved under the brand name [Campath[®]](#), which is indicated as a single agent for the treatment of B-cell chronic lymphocytic leukemia. The Campath drug label will also be updated to include these risks in the *Adverse Reactions* section under *Postmarketing Experience*.
- Healthcare providers 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. Patients should be promptly evaluated if they complain of symptoms consistent with these conditions.
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- 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; and
 - Sudden severe headache or neck pain
- The safety update is based on the identification of 13 cases of ischemic and hemorrhagic stroke or arterial dissection that occurred shortly after the patient received Lemtrada. These cases were reported in the FDA Adverse Event Reporting System database.
 - 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. One case resulted in death.
 - Most of the cases did not provide sufficient detail to allow a full assessment of individual risk factors. However, the occurrence of these adverse events within one day of Lemtrada administration suggests an association.
 - The adverse events occurred within the same time frame as cytokine release syndrome, which is known to occur after Lemtrada administration and may contribute to these adverse events. However, in many cases, insufficient information was reported to determine whether cytokine release syndrome occurred together with stroke or arterial dissection.
- Cases of ischemic stroke and intracerebral hemorrhage have also been reported in patients treated with Campath. These cases either had potential contributing factors, including underlying risk factors and concomitant medications, or the reports were missing this information.

- For these reasons, a causal association between Campath and stroke could not be established.



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