(_____)

Generic Name:
Alemtuzumab
Trade Name:
Lemtrada
Company:
Genzyme
Notes:

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 alemtuzumab. These problems can lead to permanent disability and even death.

As a result, the agency has added a new warning about these risks to the prescribing information in the drug label and to the patient Medication Guide. FDA also added the risk of stroke to the existing boxed warning, its most prominent warning.

Alemtuzumab is also approved under the brand name Campath, which was approved in May 2001 to treat 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 immediately 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.

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

Health professionals should advise patients at every alemtuzumab 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 5 years since FDA approved alemtuzumab in 2014 to treat relapsing forms of MS, the agency has identified 13 worldwide cases of ischemic and hemorrhagic stroke or arterial dissection that occurred shortly after the patient received alemtuzumab. This number includes only reports submitted to FDA, so additional cases the agency is unaware of may have occurred. Twelve of these cases reported symptoms within 1 day of receiving the drug.

Medication Monitor Categories:
Alerts and Recalls

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