

## FDA warns of rare stroke risk with MS drug

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(HealthDay)—A new warning has been added to the multiple sclerosis drug Lemtrada (alemtuzumab) after rare reports of patients suffering strokes and tears in the lining of the arteries in the head and neck, the

U.S. Food and Drug Administration said.

Most patients with these problems—which can lead to permanent disability and death—developed symptoms within a day of receiving an initial infusion of Lemtrada, the agency said. In one patient, symptoms occurred three days after receiving the drug.

One MS specialist said the information is important to people with MS, but it shouldn't mean they must immediately stop using the drug.

"One must always weigh the risks and benefits of treatment in relation to the risk of the underlying disease process," said Dr. Asaff Harel, a neurologist at Lenox Hill Hospital in New York City. He said that for many patients, Lemtrada is a really effective therapy, so "the benefits may outweigh [potential risks](#) for some patients."

In the meantime, the FDA said it is mandating a new warning about these risks to the prescribing information on the drug label and to the patient Medication Guide. The risk of stroke has also been added to the existing boxed warning, the agency said.

Alemtuzumab is also approved under the brand name Campath to treat a type of cancer called B-cell chronic lymphocytic leukemia (B-CLL). The label of that [drug](#) will also be updated to include the risk of stroke and tears in the lining of the head (arterial dissection), the FDA said.

If patients taking alemtuzumab develop signs or symptoms of a stroke or arterial dissection, they or their caregivers must seek [emergency treatment](#) as soon as possible.

Symptoms can include: sudden numbness or weakness in the face, arms, or legs, especially 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.

At every Lemtrada infusion, [health care providers](#) should advise [patients](#) to seek immediate emergency medical help if they develop symptoms of stroke or arterial dissection, the FDA said.

**More information:** The U.S. National Institute of Neurological Disorders and Stroke has more on [multiple sclerosis](#).

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