December 4, 2018

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Dear provider of healthcare services,

This communication intends to notify you that the United States Food and Drug Administration (FDA) is adding a new warning to the label of the multiple sclerosis (MS) medicine Lemtrada™ (alemtuzumab), as well as an expansion in the Boxed Warning of this medicine.

The FDA is warning that shortly after receiving Lemtrada™, rare but serious cases of stroke and tears in the lining of arteries in the head and neck have occurred in patients with MS. These problems can lead to permanent disability and even death.

Alemtuzumab is also available under the brand name Campath™ for the treatment of B-cell chronic lymphocytic leukemia, and the label of Campath™ will also be updated to include these risks.

RECOMMENDATIONS FOR HEALTHCARE PROFESSIONALS
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, and promptly evaluate patients who complain of symptoms consistent with these conditions.
Symptoms consistent with ischemic or hemorrhagic stroke or cervicocephalic arterial dissection
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
Encourage patients to read the patient Medication Guide they receive with each Lemtrada prescription, which explains the benefits and risks of the medicine.
Report side effects from Lemtrada™ to the FDA MedWatch program.

For more information regarding this and other safety communications, please visit the FDA website (www.fda.gov). To keep up to date with FDA Safety Communications, we recommend you subscribe to MedWatch Safety Alerts to receive these communications in a timely manner. You can easily subscribe to these alerts at https://www.fda.gov/Safety/MedWatch/ucm228488.htm.

On PharmPix we are compromised with the health and wellness of our insured. It is our priority to offer high quality services and to promote practices for health promotion and diseases prevention. If you have any doubt or wish to have more information regarding this document, you can call us to 787-522-5252, extension 138.

Regards,

Pharmacy Department

References:
- FDA warns about rare but serious risks of stroke and blood vessel wall tears with multiple sclerosis drug Lemtrada (alemtuzumab). US Food and Drug Administration. (11/29/2018). Available at: https://www.fda.gov/Drugs/DrugSafety/ucm624247.htm

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