ProCare Rx

URGENT NOTICE

TYPE: DRUG SAFETY COMMUNICATION

Lower Risk for Stroke and Death, but Higher Risk for GI Bleeding Compared to Warfarin

Drug Name: Pradaxa (dabigatran)

Audience: Cardiology, Patient, Pulmonology, Internal Medicine, Orthopedics, Neurology

Date: **05/13/2014**

ISSUE

The FDA recently completed a new study in Medicare patients comparing Pradaxa to warfarin, for risk of ischemic or clot-related stroke, bleeding in the brain, major gastrointestinal (GI) bleeding, myocardial infarction (MI), and death. The new study included information from more than 134,000 Medicare patients, 65 years or older, and found that among new users of blood-thinning drugs, Pradaxa was associated with a lower risk of clot-related strokes, bleeding in the brain, and death, than warfarin. The study also found an increased risk of major gastrointestinal bleeding with use of Pradaxa as compared to warfarin. The MI risk was similar for the two drugs.

Importantly, the new study is based on a much larger and older patient population than those used in FDA's earlier review of post-market data, and employed a more sophisticated analytical method to capture and analyze the events of concern. This study's findings, except with regard to MI, are consistent with the clinical trial results that provided the basis for Pradaxa's approval. As a result of these latest findings, the FDA still considers Pradaxa to have a favorable benefit to risk profile and have made no changes to the current label or recommendations for use.

BACKGROUND

Pradaxa and warfarin are used to reduce the risk of stroke and blood clots in patients with a common type of abnormal heart rhythm called non-valvular atrial fibrillation (AF).

RECOMMENDATION

Patients should not stop taking Pradaxa (or warfarin) without first talking with their health care professionals. Stopping the use of blood-thinning medications such as Pradaxa and warfarin can increase the risk of stroke and lead to permanent disability and death. Health care professionals who prescribe Pradaxa should continue to follow the dosing recommendations in the drug label.