MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

Pradaxa (dabigatran etexilate mesylate): Drug Safety Communication - Safety Review of Post-Market Reports of Serious Bleeding Events

[Updated 11/02/2012]

FDA評估使用dabigatran (Pradaxa)和warfarin造成嚴重出血的風險。這項評估的資料來自於FDA's Mini-Sentinel pilot of the Sentinel Initiative。評估結果顯示，「剛開始使用dabigatran (Pradaxa)造成的出血發生率」不高於「剛開始使用warfarin造成出血的發生率」，此結果與大型Pradaxa臨床試驗(RELY tiral)結果一致。FDA將持續評估dabigatran (Pradaxa)的安全性。

醫療人員應按照仿單建議給予劑量，特別是腎功能不全的患者，以減少出血的風險。心房震顫(atrial fibrillation)患者不應自行停藥。停止使用Pradaxa可能增加中風風險，導致永久性殘疾與死亡。

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The FDA evaluated new information about the risk of serious bleeding associated with use of the anticoagulants (blood thinners) dabigatran (Pradaxa) and warfarin (Coumadin, Jantoven, and generics). This assessment was done using insurance claims and administrative data from FDA's Mini-Sentinel pilot of the Sentinel Initiative. The results of this assessment indicate that bleeding rates associated with new use of Pradaxa do not appear to be higher than bleeding rates associated with new use of warfarin, which is consistent with observations from the large clinical trial used to approve Pradaxa (the RE-LY trial). FDA is continuing to evaluate multiple sources of data in the ongoing safety review of this issue. See the Data Summary in the 11/02/2012 Drug Safety Communication below for additional information.

FDA has not changed its recommendations regarding Pradaxa. Pradaxa provides an important health benefit when used as directed. Healthcare professionals who prescribe Pradaxa should carefully follow the dosing recommendations in the drug label, especially for patients with renal impairment (when kidneys don't function normally) to reduce the risk of bleeding. Patients with atrial fibrillation should not stop taking Pradaxa without first talking to their healthcare professional. Stopping use of anticoagulant medications such as Pradaxa can increase the risk of stroke. Strokes can lead to permanent disability and death.