Bleeding Precaution Added to Clopidogrel Label

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A precaution has been added to the clopidogrel label regarding the increased risk of major bleeding when this platelet aggregation inhibitor is used with aspirin in a certain high-risk patients.

Clopidogrel, an antiplatelet drug marketed as Plavix by Sanofi-Synthelabo Inc., is approved by the Food and Drug Administration for reduction of atherothrombotic events in patients with a recent myocardial infarction, recent stroke, or peripheral arterial disease; and in patients with acute coronary syndrome.

Specifically, the addition to the clopidogrel label reads, "In patients with recent TIA [transient ischemic attack] or stroke who are at high risk for recurrent ischemic events, the combination of aspirin and Plavix has not been shown to be more effective than Plavix alone, but the combination has been shown to increase major bleeding."

In the Clopidogrel in Unstable Angina to Prevent Recurrent Ischemic Events (CURE) study and in the Clopidogrel Versus Aspirin in Patients at Risk of Ischemic Events (CAPRIE) study, there was an increased risk of bleeding and a decreased benefit with concomitant use of clopidogrel with aspirin compared with aspirin alone in patients aged 75 years and older, according to an FDA spokesperson.

The results of another study support these findings regarding the risk of bleeding with aspirin and clopidogrel, the spokesperson said. That study, the Management of Atherothrombosis With Clopidogrel in High-Risk Patients With Recent Transient Ischemic Attack or Ischemic Stroke (MATCH) trial, compared clopidogrel plus aspirin with clopidogrel alone in patients with recent ischemic stroke or TIA. Clopidogrel was approved in 1997. ■