



The FDA Safety Information and Adverse Event Reporting Program

Plavix (clopidogrel): Reduced effectiveness in patients who are poor metabolizers of the drug

[03/12/2010]

Plavix 可降低心臟病、不穩定型心絞痛、中風、心血管疾病死亡之風險。

依據研究報靠顯示，Clopidogrel 使用於肝臟酵素 CYP2C19 代謝活性較低之患者，其藥品療效會降低。經 FDA 評估含 Clopidogrel 成分藥品之仿單應加刊以下內容：

- 對 Plavix 代謝性較差的患者會降低療效，無法有效在體內將 Plavix 轉成活性狀態。
- 醫療專業人員可測試 CYP2C19 功能之確認基因差異。
- 對 Plavix 代謝性較差的患者，醫療專業人員可以考慮使用其他抗血小板藥品或更改劑量。

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AUDIENCE : Cardiology healthcare professionals, patients

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The U.S. Food and Drug Administration (FDA) has added a *Boxed Warning* to the label for Plavix, the anti-blood clotting medication. The *Boxed Warning* is about patients who do not effectively metabolize the drug (i.e. "poor metabolizers") and therefore may not receive the full benefits of the drug.

The *Boxed Warning* in the drug label will include information to:

- Warn about reduced effectiveness in patients who are poor metabolizers of Plavix. Poor metabolizers do not effectively convert Plavix to its active form in the body.
- Inform healthcare professionals that tests are available to identify genetic differences in CYP2C19 function.
- Advise healthcare professionals to consider use of other anti-platelet medications or alternative dosing strategies for Plavix in patients identified as poor metabolizers.

Plavix is given to reduce the risk of heart attack, unstable angina, stroke, and cardiovascular death in patients with cardiovascular disease. Plavix works by decreasing the activity of blood cells called platelets, making platelets less likely to form blood clots.

For Plavix to work, enzymes in the liver (particularly CYP2C19) must convert (metabolize) the drug to its active form. Patients who are poor metabolizers of the drug, do not effectively convert Plavix to its active form. In these patients, Plavix has less effect on platelets, and therefore less ability to prevent heart attack, stroke, and cardiovascular death. It is estimated that 2 to 14% of the population are poor metabolizers; the rate varies based on racial background.