



The FDA Safety Information and  
Adverse Event Reporting Program

## **Plavix (clopidogrel): Drug Safety Communication - Long-term Treatment Does Not Change Risk of Death**

[Posted 11/06/2015]

FDA 針對 clopidogrel (Plavix) 的長期臨床試驗進行系統性分析，此分析結果顯示，長期使用 clopidogrel 不會改變有心臟疾病或是心血管風險病人的死亡率。FDA 評估審視過雙重抗血小板藥物治療文獻與其他臨床試驗後也提出建議，表示長期使用 clopidogrel 與癌症的風險或癌症病人的死亡率無明顯相關性。

### **建議**

FDA 建議，病人不應該自行停用 clopidogrel 或其他抗血小板藥物，擅自停藥可能增加心臟病發作與血液凝集的風險，若對於 clopidogrel 的使用有疑慮，需與專業醫療人員討論。醫療人員在處方抗血小板藥物前，應考量藥品的治療效益與風險。

[Posted 11/06/2015]

## **Plavix (clopidogrel): Drug Safety Communication - Long-term Treatment Does Not Change Risk of Death**

**AUDIENCE:** Cardiology, Hematology, Surgery

**ISSUE:** An FDA review has determined that long-term use of the blood-thinning drug Plavix (clopidogrel) does not increase or decrease overall risk of death in patients with, or at risk for, heart disease. FDA evaluation of the Dual Antiplatelet Therapy (DAPT) trial and several other clinical trials also does not suggest that clopidogrel increases the risk of cancer or death from cancer.

In order to investigate the increased risk of death and cancer-related death reported with clopidogrel in the DAPT trial, FDA examined the results of the DAPT trial and other large, long-term clinical trials of clopidogrel with data available on rates of death, death from cancer, or cancer reported as an adverse event.

FDA performed meta-analyses of other long-term clinical trials to assess the effects of clopidogrel on death rates from all causes. The results indicate that long-term (12 months or longer) dual antiplatelet therapy with clopidogrel and aspirin do not appear to change the overall risk of death when compared to short-term (6 months or less) clopidogrel and aspirin, or aspirin alone. Also, there was no apparent increase in the risks of cancer-related deaths or cancer-related adverse events with long-term treatment.

FDA is working with the manufacturers of clopidogrel to update the label to reflect the results of the mortality meta-analysis.

**BACKGROUND:** Clopidogrel is an antiplatelet medicine used to prevent blood clots in patients who have had a heart attack, stroke, or problems with the circulation in the arms and legs. It works by helping to keep the platelets in the blood from sticking together and forming clots that can occur with certain medical conditions.

**RECOMMENDATION:** Patients should not stop taking clopidogrel or other antiplatelet medicines because doing so may result in an increased risk of heart attacks and blood clots. Talk with your health care professional if you have any questions or concerns about clopidogrel.

Health care professionals should consider the benefits and risks of available antiplatelet medicines before starting treatment. See the [Drug Safety Communication](#) for more information, including Additional Information for Patients, Caregivers, and Health Care Professionals, and a Data Summary.