Xolair (omalizumab): Drug Safety Communication - Slightly Elevated Risk of Cardiovascular and Cerebrovascular Serious Adverse Events

[Posted 09/26/2014]

一項 FDA 的安全性回顧研究顯示，使用 Xolair (omalizumab)治療，與沒有使用 Xolair 的氣喘患者比較，心血管與腦血管事件風險有些微上升。因此 FDA 已在藥物仿單增加此訊息。

這項回顧研究結果顯示，有無使用 Xolair (omalizumab)治療，其癌症罹患率沒有差異。然而此結果受限於 5 年期研究，FDA 無法排出 Xolair 的致癌性。

背景

Xolair 是一種注射藥物，用於吸入性類固醇無法控制症狀之 12 歲以上中重度氣喘病人。

建議

病人應持續使用 Xolair，有問題可以向醫療專業人員討論。

[Posted 09/26/2014]

AUDIENCE: Allergy and Immunology, Pharmacy, Health Professional

ISSUE: An FDA review of safety studies suggests a slightly increased risk of problems involving the heart and blood vessels supplying the brain among patients being treated with the asthma drug Xolair (omalizumab) than in those who were not treated with Xolair. As a result, FDA has added information about these potential risks to the drug label.

The review found no difference in the rates of cancer between those patients being treated with Xolair and those who were not being treated with Xolair. However, due to limitations in the 5-year study, FDA cannot rule out a potential risk of cancer with Xolair, so this information was added to the Warnings and Precautions section of the drug label.

BACKGROUND: Xolair is an injectable medicine for patients 12 years of age and older with moderate to severe persistent allergic asthma whose asthma symptoms are not controlled by asthma medicines called inhaled corticosteroids.

RECOMMENDATION: Patients taking Xolair should continue to take the medication as prescribed and discuss any questions or concerns with their health care professionals.

Omalizumab (Xolair) 樂無喘