



**Lexiscan (regadenoson) and Adenoscan (adenosine): Drug Safety Communication –
Rare but Serious Risk of Heart Attack and Death**

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FDA警告，心臟核壓測試劑(cardiac nuclear stress test agents)，如Lexiscan (regadenoson)和Adenoscan (adenosine)，會造成罕見但嚴重之心臟病發作和死亡風險。FDA已核准修改藥物仿單，以反應這些嚴重事件並更新使用藥物的建議。由於資料有限，FDA無法確認Lexiscan和Adenoscan造成心臟病和死亡的風險差異。

Lexiscan和Adenoscan的仿單在先前已標示心臟病發作和死亡的風險訊息。然而FDA不良事件通報系統(FAERS)與醫學文獻的近期報告，促使仿單修改並更新使用建議。

背景

FDA核准Lexiscan和Adenoscan作為心臟核壓測試劑(cardiac nuclear stress test agents)，用於無法適度運動的病人。Lexiscan和Adenoscan藉由擴張心臟動脈並增加血流量，協助確認心臟動脈是否阻塞。Lexiscan和Adenoscan會讓血液主要流經健康且未阻塞的動脈，減少血液流經阻塞的動脈。這種血流減少的情形可能導致心臟病發作，有可能致命。

建議

篩選所有受試者，評估是否適合使用Lexiscan或Adenoscan。避免用於不穩定型心絞痛或者有心血管不穩定相關症狀的患者，因為這些患者有更高的風險產生嚴重心血管不良反應。使用Lexiscan或Adenoscan之前，須先具備心臟復甦設備和受過訓練的人員。

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AUDIENCE: Cardiology, Pharmacy, Radiology

ISSUE: The FDA is warning health care professionals of the rare but serious risk of heart attack and death with use of the cardiac nuclear stress test agents Lexiscan (regadenoson) and Adenoscan (adenosine). FDA has approved changes to the drug labels to reflect these serious events and updated recommendations for use of these agents. At this time, data limitations prevent FDA from determining if there is a difference in risk of heart attack or death between Lexiscan and Adenoscan.

The Warnings & Precautions section of the Lexiscan and Adenoscan labels previously contained information about the possible risk of heart attack and death with use of these drugs. However, recent reports of serious adverse events in the FDA Adverse Event Reporting System (FAERS) database and the medical literature prompted approval changes to the drug labels to include updated recommendations for use.

BACKGROUND: Lexiscan and Adenoscan are FDA approved for use during cardiac nuclear stress tests in patients who cannot exercise adequately. Lexiscan and Adenoscan help identify coronary artery disease. They do this by dilating the arteries of the heart and increasing blood flow to help identify blocks or obstructions in the heart's arteries. Lexiscan and Adenoscan cause blood to flow preferentially to the healthier, unblocked or unobstructed arteries, which can reduce blood flow in the obstructed artery. In some cases, this reduced blood flow can lead to a heart attack, which can be fatal.

RECOMMENDATIONS: Screen all nuclear stress test candidates for their suitability to receive Lexiscan or Adenoscan. Avoid using these drugs in patients with signs or symptoms of unstable angina or

cardiovascular instability, as these patients may be at greater risk for serious cardiovascular adverse reactions. Cardiac resuscitation equipment and trained staff should be available before administering Lexiscan or Adenoscan.