MedWatch The FDA Safety Information and Adverse Event Reporting Program

Reclast (zoledronic acid): Drug Safety Communication - New Contraindication and Updated Warning on Kidney Impairment

[Posted 09/01/2011]

FDA 通知醫療人員與病患，zolendronic acid (Reclast)仿單更新：zolendronic acid (Reclast)會增加腎衰竭的風險。FDA 已接收到數個報告，使用 zolendronic acid (Reclast)的案例產生了急性腎衰竭，需作透析或者造成致命性的結果。

新修訂後的仿單規定，zolendronic acid(Reclast)禁用於肌酐酸清除率(creatinine clearance)小於 35 ml/min、或有急性腎衰竭的患者。醫療人員應先檢視患者的狀況再給予 zolendronic acid (Reclast)，並且監測使用者的腎功能。

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AUDIENCE: Endocrinology, Pharmacy, Patient

ISSUE: FDA notified healthcare professionals and patients of an update to the drug label for Reclast (zoledronic acid) regarding the risk of kidney failure. Cases of acute renal failure requiring dialysis or having a fatal outcome following Reclast use have been reported to FDA. The revised label states that Reclast is contraindicated in patients with creatinine clearance less than 35 mL/min or in patients with evidence of acute renal impairment. The label also recommends that healthcare professionals screen patients prior to administering Reclast in order to identify at-risk patients.

The Reclast Medication Guide for patients is being updated to contain information about the risk of severe kidney problems. In addition, the manufacturer of Reclast will issue a Dear Healthcare Provider letter to inform healthcare professionals about this risk.

RECOMMENDATIONS: Reclast is contraindicated in patients with creatinine clearance less than 35 mL/min, or in patients with evidence of acute renal impairment. Healthcare professionals should screen patients prior to administering Reclast in order to identify at-risk patients. Healthcare professionals should also monitor renal function in patients who are receiving Reclast。