MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

Terbutaline: Label change – warnings against use for treatment of preterm labor

[02-23-2011]

美國 FDA 近期發布terbutaline 成分藥品之用藥安全資訊，依據美國不良反應通報資料，發現有醫師未依該藥品所核准之適應症，將其使用於預防或治療孕婦早產，導致孕婦發生嚴重心臟問題，甚至死亡之通報案例。因此，美國FDA要求含該成分之注射製劑及口服製劑藥品，應於仿單「禁忌」及「加框警語」等部分，加註有關該成分藥品不可使用於預防或治療孕婦早產等相關警語。

Terbutaline: Label change – warnings against use for treatment of preterm labor

AUDIENCE: OBGYN, Family Practice

[Posted: 02-23-2011]

FDA notified healthcare professionals that injectable terbutaline should not be used in pregnant women for prevention or prolonged treatment (beyond 48-72 hours) of preterm labor in either the hospital or outpatient setting because of the potential for serious maternal heart problems and death. In addition, oral terbutaline should not be used for prevention or any treatment of preterm labor because it has not been shown to be effective and has similar safety concerns.Death and serious adverse reactions, including increased heart rate, transient hyperglycemia, hypokalemia, cardiac arrhythmias, pulmonary edema, and myocardial ischemia have been reported after prolonged administration of oral or injectable terbutaline to pregnant women.

Based on FDA review, FDA has concluded that the risk of serious adverse events outweighs any potential benefit to pregnant women receiving prolonged treatment with terbutaline injection (beyond 48-72 hours), or acute or prolonged treatment with oral terbutaline. FDA is requiring the addition of a new Boxed Warning and Contraindication to the terbutaline drug labels to warn healthcare professionals about these risks.