Magnesium Sulfate: Drug Safety Communication - Recommendation Against Prolonged Use in Pre-term Labor

[Posted 05/30/2013]

FDA建議，硫酸鎂用於孕婦停止妊娠足月前分娩(stop pre-term labor)時，不可超過5-7天。孕婦使用硫酸鎂超過5-7天，可能對正在發育中的胎兒造成低血鈣和骨骼問題，包含骨質流失(osteopenia)、骨折。極短期的治療對於胎兒的傷害仍無法確認。

FDA**未**核可硫酸鎂用於孕婦停止妊娠足月前分娩；而是核准用於子癇前症的癲癇發作。

建議

新的安全訊息顯示，硫酸鎂可能對正在發育中的胎兒造成低血鈣和骨骼問題，因此以下資料將加註於Magnesium Sulfate Injection, USP 50%仿單：

- 一項新警示：硫酸鎂用於孕婦停止妊娠足月前分娩(stop pre-term labor)超過5-7天，可能對正在發育中的胎兒造成低血鈣和骨骼問題
- 由於潛在的致畸姓，懷孕分級將由A改至**D**。懷孕分級D的意思為：已有證據證實該藥品對人類胎兒有危險性，但若潛在利益高於潛在風險時，孕婦可考慮使用。
- FDA**未**核可硫酸鎂用於孕婦停止妊娠足月前分娩，且其有效性和安全性尚未建立。當孕婦於非核可適應症的情形下使用硫酸鎂時，只應由專業的產科人員於適當產科護理設備的環境中，注射硫酸鎂。

孕婦應與醫療人員討論即將分娩的可能性及任何治療的風險與益處。

[Posted 05/30/2013]

AUDIENCE: OB/GYN, Nursing, Risk Manager

ISSUE: FDA is advising health care professionals against using magnesium sulfate injection for more than 5-7 days to stop pre-term labor in pregnant women. Administration of magnesium sulfate injection to pregnant women longer than 5-7 days may lead to low calcium levels and bone problems in the developing baby or fetus, including thin bones (osteopenia), and fractures. The shortest duration of treatment that can result in harm to the baby is not known.

BACKGROUND: This use of the drug is off-label, and is not an FDA-approved use of the drug. Magnesium sulfate is approved to prevent seizures in preeclampsia, a condition in which the pregnant woman develops high blood pressure and protein in the urine, and for control of seizures in eclampsia. Both preeclampsia and eclampsia are life-threatening complications that can occur during pregnancy. Preeclampsia can lead to eclampsia, seizures, stroke, multiple organ failure, and death of the woman and/or baby.

RECOMMENDATIONS: In light of this new safety information about low calcium levels and bone problems in the developing baby, the following information is being added to the drug label for Magnesium Sulfate Injection, USP 50%:

- A new Warning stating that continuous administration of magnesium sulfate injection beyond 5-7 days in pregnancy for the treatment of pre-term labor can cause low calcium levels and bone changes in the baby.
- A new Teratogenic Effects section conveying the potential harm to developing babies by changing

the Pregnancy Category to D from A. Pregnancy Category D means there is positive evidence of human fetal risk, but the potential benefits from using the drug in pregnant women may be acceptable in certain situations despite its risks.

- A new Labor and Delivery section emphasizing that continuous administration of magnesium sulfate injection to treat pre-term labor is not approved and that the safety and efficacy of use for this indication are not established. When used in pregnant women for conditions other than its approved indication, magnesium sulfate injection should be administered only by trained obstetrical personnel in a hospital setting with appropriate obstetrical care facilities.

Pregnant women should discuss with their health care professional the possibility of going into labor before term and the risks and benefits of any treatments that may be used.