



The FDA Safety Information and Adverse Event Reporting Program

Valproate Products: Drug Safety Communication - Risk of Impaired Cognitive Development in Children Exposed In Utero (During Pregnancy)

Including valproate sodium (Depacon), divalproex sodium (Depakote, Depakote CP, and Depakote ER), valproic acid (Depakene and Stavzor), and their generics

[Posted 06/30/2011]

FDA 近期發布 valproate 成分抗癲癇藥品之用藥資訊，依據流行病學研究，發現癲癇病患於懷孕期間使用含該成分藥品，可能會些微降低幼兒認知能之風險，因此要求含該成分藥品仿單加刊相關警語與注意事項。食品藥物管理局將儘速蒐集國內外安全相關資料，再評估是否進行仿單內容更新。

經查，衛生署核准含成分 valproic acid 及 divalproex sodium 等成分藥品之藥物許可證共 38 張，所核適應症為「癲癇大發作、小發作、混合型及顛葉癲癇」。全國藥物不良反應通報資料，尚無孕婦疑似使用含該成分藥品導致出生之幼兒認知能力受損之通報案件。衛生署核准該成分藥品仿單之「懷孕與哺乳」欄位中已記載「輕微降低語言能力...」與「零星的兒童自閉症案例報告」等資訊，食品藥物管理局將進一步是否加強刊載。

FDA 提醒醫師，處方含該成分藥品於育齡婦女前，應詢問病人是否懷孕或有懷孕準備，並告知使用該藥品可能對出生後之胎兒認知能力發展風險。此外病人懷孕時若使用該成分藥品亦可能提升致畸胎風險；病患服藥期間，應使用安全避孕方法，如果懷孕應儘速告知醫師，討論其他治療方式。

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AUDIENCE: OBGYN, Neurology, Psychiatry

[Posted 06/30/2011]

FDA notified healthcare professionals that children born to mothers who take the anti-seizure medication valproate sodium or related products (valproic acid and divalproex sodium) during pregnancy have an increased risk of lower cognitive test scores than children exposed to other anti-seizure medications during pregnancy. This conclusion is based on the results of epidemiologic studies that show that children born to mothers who took valproate sodium or related products throughout their pregnancy tend to score lower on cognitive tests (IQ and other tests) than children born to mothers who took other anti-seizure medications during pregnancy. See the Drug Safety Communication for a data summary and additional information.

Healthcare professionals should inform women of childbearing age of the increased risk for adverse effects on cognitive development with prenatal valproate exposure, and should continue to counsel women of childbearing potential taking valproate about the increased risk of major malformations, including neural tube defects, when valproate is used during pregnancy. In addition, healthcare professionals should weigh the benefits and risks of valproate when prescribing this drug to women of childbearing age, particularly when treating a condition not usually associated with permanent injury or death. Alternative medications that have a lower risk of adverse birth outcomes should be considered. Patients should not stop taking valproate without talking to a healthcare professional.