MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

Valproate Anti-Seizure Products: Drug Safety Communication - Contraindicated for Pregnant Women for Prevention of Migraine Headaches

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

[Posted 05/06/2013]

FDA建議，valproate sodium及其相關產品禁用於治療懷孕婦女的偏頭痛。近期有一項研究指出，懷孕婦女使用這些藥物，會造成胎兒智商下降。藥品仿單將加註此警訊，並且將懷孕分級由D改至**X**。

Valproate用於癲癇、雙極性精神疾病之躁症，懷孕分級仍維持在D。

建議

Valproate sodium及其相關產品禁用於治療懷孕婦女的偏頭痛；癲癇、雙極性精神疾病之躁症的孕婦使用其他治療無效之後才可使用valproate。

目前正在使用valproate的懷孕婦女不應自行停藥，但應立即告知醫療人員。突然停用valproate可能會對媽媽跟胎兒造成嚴重致命性的藥物副作用。

[Posted 05/06/2013]

AUDIENCE: Health Professional, Neurology, Pharmacy, Patient

ISSUE: FDA is advising health care professionals and women that the anti-seizure medication valproate sodium and related products, valproic acid and divalproex sodium, are contraindicated and should not be taken by pregnant women for the prevention of migraine headaches. Based on information from a recent study, there is evidence that these medications can cause decreased IQ scores in children whose mothers took them while pregnant. Stronger warnings about use during pregnancy will be added to the drug labels, and valproate's pregnancy category for migraine use will be changed from "D" (the potential benefit of the drug in pregnant women may be acceptable despite its potential risks) to "X" (the risk of use in pregnant women clearly outweighs any possible benefit of the drug).

Valproate products will remain in pregnancy category D for treating epilepsy and manic episodes associated with bipolar disorder.

BACKGROUND: Valproate products are approved for the treatment of certain types of epilepsy, the treatment of manic episodes associated with bipolar disorder, and the prevention of migraine headaches. They are also used off-label (for uses not approved by FDA) for other conditions, particularly other psychiatric conditions.

This alert is based on the final results of the Neurodevelopmental Effects of Antiepileptic Drugs (NEAD) study showing that children exposed to valproate products while their mothers were pregnant had decreased IQs at age 6 compared to children exposed to other anti-epileptic drugs. For additional details, see the Drug Safety Communication Data Summary section.

RECOMMENDATION: Valproate products should not be used in pregnant women for prevention of migraine headaches and should be used in pregnant women with epilepsy or bipolar disorder only if other treatments have failed to provide adequate symptom control or are otherwise unacceptable.

Women who are pregnant and taking a valproate medication should not stop their medication but should talk to their health care professionals immediately. Stopping valproate treatment suddenly can cause serious and life-threatening medical problems to the woman or her baby.