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FDA: Pregnant women must not take migraine drug

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Singapore: The US FDA is alerting healthcare providers and patients that medications including and related to valproate sodium can cause decreased intelligence quotient (IQ) scores in children whose mothers took the medication during pregnancy.

Therefore, the FDA is cautioning against the use of these drugs for the prevention of migraine headaches in pregnant women. Valproate products include valproate sodium (Depacon), divalproex sodium (Depakote, Depakote CP, and Depakote ER), valproic acid (Depakene and Stavzor), and their generics.

Valproate products have several FDA-approved uses including, prevention of migraine headaches, treatment of epilepsy (seizures), and treatment of manic episodes associated with bipolar disorder (manic-depressive disorder).

Medicines that contain valproate already have a boxed warning for fetal risk, including birth defects. The recently published Neurodevelopmental Effects of Antiepileptic Drugs (NEAD) study found further evidence of the IQ risk, leading to strengthened warnings.

The FDA's strengthened recommendations are based on the final results of the NEAD study, which showed that children exposed to valproate products in utero had decreased IQ at age six as compared to children who were exposed to other antiepileptic drugs. The difference in average IQ between the children, who had been exposed to valproate and the children who had been exposed to other antiepileptic drugs, varied between eight-and-11 points depending on the antiepileptic drug.