Position Statement on the Use of Valproate by Women of Childbearing Potential

The American Epilepsy Society (AES) recognizes that several research studies and international pregnancy registries have demonstrated that valproate (valproic acid, divalproex sodium) has a substantial risk of causing major congenital malformations (birth defects), lower intelligence quotient (IQ) scores and an increased risk of autism in children born to mothers taking this medication during pregnancy for any reason. The AES endorses the warnings provided by the United States Food & Drug Administration (FDA).

The FDA has required the following three sentences be placed in the prescribing information of valproate formulations:

1. Valproate use is contraindicated during pregnancy in women being treated for prophylaxis of migraine headaches. Women with epilepsy or bipolar disorder who are pregnant, or who plan to become pregnant, should not be treated with valproate unless other treatments have failed to provide adequate symptom control or are otherwise unacceptable. In such women, the benefits of treatment with valproate during pregnancy may still outweigh the risks.

2. Because of the risk to the fetus of decreased IQ and major congenital malformations (including neural tube defects), which may occur very early in pregnancy, valproate should not be administered to a woman of childbearing potential unless the drug is essential to the management of her medical condition. This is especially important when valproate used is considered for a condition not usually associated with permanent injury or death (e.g., migraine).

3. Dietary folic acid supplementation, both prior to conception and during pregnancy, should be routinely recommended for patients using valproate.

The AES recommends that before healthcare providers treat any female of childbearing potential with valproate they must inform the patient of these risks.

Reference:

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