

Learning Notice: 04/18

SODIUM VALPROATE (Epilim®) DURING PREGNANCY

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Actions required By Whom: Hospital Group CEOs, Hospital CEOs and Managers, Clinical Directors, Obstetric & Gynaecology Clinicians in all Directorates and Maternity Hospitals and Maternity Units, and Directors of Nursing and Midwifery.

By When: For **IMMEDIATE ACTION** in Maternity Hospitals and Acute Hospitals with Maternity Units/Services. Please ensure that this is brought to the attention of all relevant staff.

Learning:

The Health Products Regulatory Authority (HPRA) has issued new regulations in relation to valproate (Epilim®). The regulations are part of a Pregnancy Prevention Programme and outline prescriber's responsibilities in relation to prescribing this medication to women. It is important that all women who have been prescribed valproate are:

- Made aware of the teratogenic risks associated with taking valproate
- Attend for review annually with an appropriate specialist. If a woman is not currently attending a specialist, please refer her to one
- Provided with appropriate contraception in line with the specified Pregnancy Prevention Programme.

Given the known dangers of this drug, it is imperative that if you have a patient who is pregnant or enquiring about becoming pregnant and is taking sodium valproate they **MUST BE REVIEWED** by the appropriate prescribing specialist. The HPRA has licensed sodium valproate for the treatment of epilepsy and bipolar disorder so the prescribing specialist would be the patient's Neurologist or Psychiatrist or General Practitioner.

Additional information for health professionals is available at:
[http://www.hpra.ie/homepage/medicines/special-topics/valproate-\(epilim\)](http://www.hpra.ie/homepage/medicines/special-topics/valproate-(epilim)) .

The HPRA has also a Patient Guide for Women and Girls available at:
<http://www.hpra.ie/docs/default-source/Valproate/patient-guide.pdf>