Valproate (Epilim) is a medicine licensed in Ireland to treat epilepsy and bipolar disorder.

If a woman becomes pregnant while taking Epilim, their baby is at risk of serious birth defects and developmental disorders. In February 2018, the European Medicines Agency (EMA) put in place new measures to avoid exposure of babies to Epilim in the womb.

New Restrictions

The new EMA measures, which are being implemented in Ireland by the medicines regulator, the HPRA include:

- For women with epilepsy, Epilim must not be used in pregnancy unless there is no suitable alternative treatment.
- In female patients from the time they become able to have children, Epilim must not be used unless the conditions of a new Pregnancy Prevention Programme are met.

What are the main points of the new Pregnancy Prevention Programme?

- Prescribers must assess female patients for the potential of becoming pregnant, and involve the patient in evaluating her individual circumstances and supporting informed decision making,
- Pregnancy tests must be carried out before starting and during treatment as needed,
- Female patients must be informed about the risks of Epilim and what to do if planning a pregnancy or becomes pregnant
- Effective contraception must be used throughout treatment and counselling on contraception provided

- All female patients must be given the new patient information booklet and must sign an annual Risk Acknowledgement form acknowledging that they understand the risks and necessary precautions
- Importantly, all female patients must have an annual review of treatment by a **specialist.** If you are not currently attending specialist services, please contact your GP for advice and guidance in order to schedule a specialist review.

PLEASE CONTACT YOUR HEALTHCARE TEAM IF YOU HAVE ANY CONCERNS. DO NOT STOP TAKING VALPROATE WITHOUT FIRST SPEAKING WITH YOUR PRESCRIBER.

NEW Epilim information booklets (May 2018)

Please download the latest patient information booklet for women and girls, authorised by the HPRA in May 2018.

Resources for Healthcare Professionals

A new range of resources are also available from the HPRA website for prescribers and pharmacists. These resources include a new HCP Guide; posters, patient information cards and shelf-markers for pharmacists and the new risk acknowledgement form for prescribers. Further details of the Pregnancy Prevention Programme can be found here.

Other changes in Ireland to reduce the risks associated with Epilim

- New warnings on the outside of boxes including a new pictogram.
- The practice of dispensing Epilim in plastic bags is to be discontinued and the medication will be made available in its original packaging with the package insert leaflet included.
- Patient information cards will be attached to the new boxes.
- Warnings to be put on blister packs and as a short-term solution, stickers will be provided to pharmacists to use
- The Pharmacy Regulator has issued clear guidelines to pharmacists regarding their role in ensuring patients are fully informed.
- In August, the HSE undertook targeted communications with healthcare professionals and patients.

Further Information

- HPRA
- HSE Valproate page
- European Medicines Agency
- Contact your local Epilepsy Ireland office
- If you took Epilim during a previous pregnancy and are concerned about Organisation for Anticonvulsant Syndrome Ireland visit their Facebook Group page
- Contact your prescriber or your Hospital Epilepsy Helpline service
- If you are not currently attending specialist services, please contact your GP for advice and guidance in order to schedule a specialist review.