



27 May 2016

**Medicines containing valproate: risk of abnormal pregnancy outcomes
(Epilim oral range, Epilim Chrono and Epilim IV range)**

New communication materials including patient card for pharmacist to distribute

This letter is being sent in agreement with the HPRA to all pharmacists dispensing valproate based medicines

Dear Pharmacist,

In December 2014 in agreement with the HPRA, we wrote to inform you of important new information and reinforced warnings related to the safety of medicines containing valproate in females of child-bearing potential and pregnant women. That communication letter covered the following:

Summary of risks and precautions

- Children exposed to valproate in the womb are at a high risk of serious developmental disorders (occurs in up to 30/40% cases) and congenital malformations (occur in approximately 10% of cases)
- Valproate should not be prescribed to female children, female adolescents, women of child-bearing age or pregnant women unless other treatments are ineffective or not tolerated
- Valproate treatment must only be started and supervised by a doctor experienced in managing epilepsy or bipolar disorder
- The benefits of valproate treatment should be carefully balanced against the risks when prescribing valproate for the first time, at routine (at least annual) treatment reviews, when a girl reaches puberty, and when a woman plans a pregnancy or becomes pregnant
- All girls and women of child-bearing age must be informed of and understand:
 - The risks associated with taking valproate during pregnancy
 - The need to use effective contraception
 - The need for regular treatment reviews
 - The need to speak to her doctor urgently if she is planning a pregnancy or becomes pregnant

In May 2015 we wrote to inform you that educational materials were made available to healthcare professionals and patients in order to clarify the information and facilitate discussion between patients and their healthcare professional about these risks.

During the course of 2016 the outer packaging for all products in the Epilim range will also be updated to include this reinforced warning for women on the risk of adverse pregnancy outcomes.

To further improve awareness of the risks of valproate in pregnancy please find enclosed with this letter

- One pack of 25 patient cards

What you are being asked to do

- Whenever you dispense a medicine related to valproate to a girl or woman of child-bearing age give her a Patient card, unless she confirms that she already has one;
- Encourage her to read the card and enter her name and date and ensure she understands the information on the card.
- If you manage dispensing services in your organisation ensure that processes are in place to allow these requirements to be met.

Educational materials

The following educational materials have been developed to ensure prescribers and patients understand the risks associated with valproate:

- Valproate patient card (enclosed)
- Booklet for healthcare professionals (available online at www.sanofi.ie or www.hpra.ie)
- Checklist for healthcare professionals (available online at www.sanofi.ie or www.hpra.ie)
- Valproate patient guide (available online at www.sanofi.ie or www.hpra.ie)

The last three items are intended to be used by specialists when they prescribe valproate to a girl or woman of child-bearing age for the first time and at subsequent reviews (at least annually). The enclosed patient cards are for pharmacy staff to give to girls and women of child-bearing age when valproate is dispensed. These cards complement the above patient guide in reminding women of the risks associated with the use of valproate during pregnancy.


Electronic copies of all the above materials are available on www.sanofi.ie and www.hpra.ie.

Printed copies of these materials can be ordered directly from Sanofi medical information.

Tel: 01 4035 600 or e-mail UK-Medicalinformation@sanofi.com

Thank you for your co-operation in following these requirements. This will help ensure appropriate use of valproate in this patient group and minimise these significant risks.

Yours sincerely



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