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27 May 2016

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

This letter is being sent in agreement with the HPRA to GPs and specialists managing patients taking valproate- based medicines

Dear <Title> <Sname>,

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. In May 2015 educational materials were made available to healthcare professionals and patients in order to clarify the information about these risks. To further improve awareness of the risk of valproate, we are asking that you use the new communication materials outlined below to support discussion of these risks with your patients. Hard copies are being sent to relevant healthcare professionals from this week.

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.

Summary of risks and precautions

- Children exposed in utero to valproate are at a high risk of serious developmental disorders (in up to 30-40% of cases) and congenital malformations in approximately 10% of cases).
- Valproate should not be prescribed to female children, female adolescents, women of child-bearing potential or pregnant women unless other treatments are ineffective or not tolerated.
- Valproate treatment must be started and supervised by a doctor experienced in managing epilepsy or bipolar disorder.
- Carefully balance the benefits of valproate treatment against the risks when prescribing valproate for the first time, at routine treatment reviews, when a female child reaches puberty and when a woman plans a pregnancy or becomes pregnant.
- You must ensure that all female patients are informed of and understand:
    - The risks associated with valproate during pregnancy;
    - The need to use effective contraception;
    - The need for regular review of treatment; and
    - The need to rapidly consult her treating physician if she is planning a pregnancy or becomes pregnant.

This topic is important. Valproate should not be used in girls and women of child-bearing age unless other treatments are not effective or are not tolerated.

Please find enclosed with this letter:

- The Booklet for healthcare professionals on the risks of valproate in female patients;
- The Valproate Patient Guide; and
- The Checklist to be used with patients.

What you are being asked to do:

- Please read the **booklet for Healthcare Professionals** which gives:
  - a comprehensive overview of the risks of valproate in females of child-bearing potential and during pregnancy; and
  - points to consider and steps to take when deciding to treat women of child-bearing potential and girls with valproate.

- When considering treating a girl or woman of child-bearing age, give her the **Valproate Patient Guide** and ensure that she understands the information it contains. If your patient is a young girl, then ensure that the guide is given to and explained to her parent/carer.
- Whenever you conclude it is necessary to treat or continue treating a woman of child-bearing potential or a girl with valproate, use the **Checklist** to check you have given her all the necessary information and that the patient (or her parent/carer if appropriate) has fully understood it. A copy may be retained in their medical records where this is helpful in your clinical practice.

- If you manage specialist care in your organisation, ensure that processes are in place to allow these requirements to be met.

Valproate treatment must only be started and supervised by a specialist experienced in managing epilepsy or bipolar disorder. Consider the need to arrange treatment reviews with the relevant specialist for women of child-bearing potential and girls who are currently taking valproate. If a woman who is taking valproate tells you she is pregnant or would like to have a baby, refer her to the specialist responsible for her care.

It is recommended that pregnant women who are taking valproate are enrolled in the Irish Epilepsy & Pregnancy Register, which can be contacted at 1800 320 820 or www.epilepsypregnancyregister.ie

Patient Card
We have written to pharmacists who dispense valproate to ask them to give out patient information cards to girls and women of child-bearing age. These cards complement the Valproate Patient Guide mentioned above.

As with all medicines we request that you report suspected adverse events, including those observed in a baby or child and which may result from *in utero* exposure to a medicine taken by a mother. Any suspected adverse events should be reported to the Health Products Regulatory Authority (formerly the Irish Medicines Board), via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2;
Tel: + 353 1 676 4971; Fax: + 353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

Company contact point
Copies of the educational materials are available on www.sanofi.ie or by contacting our medical information department at telephone number (01) 4035600 or via e-mail to UK-Medicalinformation@sanofi.com

Copies of the educational materials are also available on www.hpra.ie.

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