HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Valproate-containing Medicines
Additional Educational Materials Available for Healthcare Professionals and Patients

The outcome of the Europe-wide review of valproate-containing medicines was communicated to healthcare professionals in December 2014 via the HPRA Drug Safety Newsletter (Edition 65) and a Direct Healthcare Professional Communication (DHPC) circulated by the Marketing Authorisation Holder (MAH) following approval by the HPRA. This review recommended strengthening of restrictions for use of valproate and further characterising the risk of birth defects and developmental disorders in the product information (Summary of Product Characteristics (SmPC) and Package Leaflet (PL)). In May 2015, educational materials were made available by the MAH (following HPRA approval) as part of the risk minimisation measures developed to inform healthcare professionals and patients about the risks associated with use of valproate by females of child-bearing potential and during pregnancy.

These educational materials have now been updated and enhanced to further support awareness and to facilitate discussion of the risks between healthcare professionals and patients. The additional educational materials include the following:

Booklet for Healthcare Professionals

- This booklet provides up to date information about the risk of neurodevelopmental disorders in children of women who have taken valproate during pregnancy, in addition to the known risk of congenital malformations in exposed babies.
- It also provides points to consider and steps to take when deciding to treat women of child-bearing potential with valproate.
- The booklet should be used in conjunction with the patient guide and checklist, as well as the complete Summary of Product Characteristics (SmPC).

Valproate Patient Guide

- This booklet includes information for all females taking any medicine containing valproate.
- Healthcare professionals should ensure that female patients treated with valproate are provided with the valproate patient guide and that they understand the information it contains. If a patient is a young girl, the guide should be explained to her parent/carer.

Valproate Patient Card

- Pharmacists are requested to distribute a valproate patient card whenever a valproate-containing medicine is dispensed to a female of child-bearing age, unless she confirms that she already has one.
- The pharmacist should encourage the patient to read the patient guide and card together, to understand the information provided and enter her name and date on the card to indicate she has read and understood the information.

Checklist for Prescribers

- If a prescribing doctor concludes it is necessary to treat, or to continue treating a woman of child-bearing age with a valproate-containing medicine, then the checklist should be used to ensure that all necessary information has been provided to the patient and/or carer and that they fully understand it.

These updated materials have been recently distributed to doctors and pharmacists by the MAH with an accompanying DHPC. The educational materials are also available from the HPRA website (www.hpra.ie).

Advice to Healthcare Professionals

- 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.
- Children exposed *in utero* to valproate are at a high risk of serious developmental disorders (in up to 30-40% of cases) and/or congenital malformations (in approximately 10% of cases).
- Valproate treatment should only be commenced and supervised by a doctor experienced in managing epilepsy or bipolar disorder.
- Before initiating treatment, the balance of the benefits of treatment with valproate must be weighed against the risks. This should also be considered at routine treatment reviews, when a female reaches puberty and when a woman plans a pregnancy or becomes pregnant. The prescribing doctor should consult the booklet for healthcare professionals.
- All female patients must be informed of and understand the risks associated with valproate during pregnancy and the steps to take if pregnancy occurs or is planned. The valproate patient guide and patient card should be provided to all female patients of child-bearing age and discussed with them to ensure full understanding of the associated risks.
- The prescribing doctor should also use the checklist available to ensure that all necessary information has been provided to the patient and/or carer.
- Further updates will be made to the outer packaging for all valproate-containing products to include a warning for women on the risk of adverse pregnancy outcomes.
- All suspected adverse reactions associated with valproate-containing medicines should be reported to the HPRA via the usual methods (www.hpra.ie).

Key Message

- Valproate-containing medicines should not be prescribed to female children, female adolescents, women of childbearing potential or pregnant women, unless other treatments are ineffective or not tolerated, due to the risk of serious developmental disorders and/or congenital malformations.
- To further improve awareness of the risks associated with use of valproate-containing medicines in females of child-bearing potential and in pregnancy, updated educational materials and patient alert cards are available and should be used by healthcare professionals to support appropriate and safe prescribing/dispensing of valproate-containing medicines, and by patients/carers to increase their knowledge of these risks.

Further details on valproate-containing medicines are available at www.hpra.ie

This section has been supplied by the HPRA for use in MIMS Ireland. However, the HPRA is independent and impartial to any other information contained in this directory.