

VALPROATE AND OF RISK OF ABNORMAL PREGNANCY OUTCOMES: NEW COMMUNICATION MATERIALS

February 2015 issue of Safety Matters advised of important new information and strengthened warnings issued by the MHRA relating to valproate (sodium valproate, valproic acid and valproate semisodium).

The review found that children exposed to valproate in utero are at a higher risk of developmental disorders and congenital malformations.

To further improve awareness of the risks of valproate in pregnancy new communication materials are available to support discussion of these risks with women of childbearing potential and girls who take valproate; <https://www.gov.uk/drug-safety-update/valproate-and-of-risk-of-abnormal-pregnancy-outcomes-new-communication-materials>.

Valproate Treatment

Valproate treatment must be started and supervised by a specialist experienced in managing epilepsy or bipolar disorder and should not be prescribed to female children, female adolescents, women of childbearing potential or pregnant women unless other treatments are ineffective or not tolerated.

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.

Support Materials

To further improve awareness of the risks of valproate in pregnancy we are asking that you use the new communication materials listed below which can be accessed via the link above to support discussion of these risks with women of childbearing potential and girls who take valproate.

Warnings are scheduled to appear on the packaging of valproate-based medicines later this year.

Healthcare professional booklet - An overview of the risks of valproate in females of childbearing potential and during pregnancy.

Checklist - To ensure all necessary information has been given and fully understood by the female patient. Completed check list to be added to the patient record.

Patient guide - To be given to the carer or patient and ensure they understand the information it contains.

Patient card - to be given to the patient when valproate dispensed (unless the woman/carers says she already has one). Encourage her to read the card and enter her name and date to reinforce her own accountability to consider the information it contains.

IMPORTANT:

You must ensure that all female patients are informed of and understand the risks associated with valproate during pregnancy by ensuring that they have:

- Understood the risks related to valproate in case of pregnancy.
- Received the patient information booklet valproate booklet for patients January 2015.
- Understood the need for regular review of treatment.
- Understood the need to use effective contraception.
- Understood the need to rapidly consult if she is planning a pregnancy, becomes pregnant or thinks she might be pregnant.
- Understood the need to keep taking her treatment until you have seen her if she becomes pregnant and that an urgent consultation will be scheduled to re-assess the benefit/risk of her therapy.

