



Valproate and Risk of Abnormal Pregnancy Outcomes: New Communication Materials

The MHRA issued guidance in January 2015 regarding high risk of developmental disorders (30 to 40% of cases) and/or congenital malformations (10% of cases) in children exposed to valproate in utero. See [Drug Safety Update 22 January 2015](#) for detailed information.



The benefits of valproate treatment in females of child bearing age* should be carefully balanced 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.

All female patients of child bearing age should be informed of and understand:

- Risks associated with valproate during pregnancy
- Need to use effective contraception
- Need for regular review of treatment
- Need to rapidly consult if planning a pregnancy or becomes pregnant (Folic acid 5mg daily should be prescribed preconception and during 1st trimester see [SIGN 143 - epilepsy in adults](#))

New communication material has been developed for healthcare professionals and patients to promote awareness of these risks and reduce inappropriate exposure of valproate during pregnancy. See [Drug Safety Update 17 February 2016](#) for detailed information. Healthcare professionals are being asked to use the new communication materials below to support discussion of these risks with women and girls of child bearing age who take valproate.

Available Resources**

- [Booklet](#) for Healthcare Professionals
- Consultation [checklist](#)
- [Guide](#) to give patients
- [Card](#) to give patients

** Can be accessed via www.medicines.org.uk (search valproate).

Printed copies can be ordered directly from Sanofi on: Tel: 0845 372 7101 or E-mail: UK-Medicalinformation@sanofi.com

* In general terms females of child bearing age refers to girls of 11 years and older

Important Key Points for Healthcare Professionals

Specialists (neurologists, psychiatrists and paediatricians)

- Read the [booklet](#) which provides a comprehensive overview of the risks of valproate in females of childbearing age and during pregnancy, including points to consider and steps to take when deciding to treat women of childbearing age and girls with valproate.
- If valproate is prescribed, use the [checklist](#) to ensure that you have given her all the necessary information and that she has fully understood it. Add the completed checklist to her medical notes.
- Give the patient a copy of the patient [guide](#) and ensure that she understands the information it contains.
- Paediatricians should also refer parents or carers to the [Medicines for Children Valproate information leaflet](#)
- Further supply of [checklist](#) and patient [guide](#) can be ordered as detailed on page 1.

General Practitioners

- Valproate should be started and supervised by a specialist experienced in managing epilepsy or bipolar disorder (Amber traffic light in the Tayside Area Formulary).
- Consider 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. (Folic acid 5mg daily should be prescribed preconception and during the 1st trimester, see [SIGN 143 - epilepsy in adults](#))

Pharmacists

- Give out a valproate patient [card](#) to all females of child bearing age when dispensing valproate unless they confirm they already have one.
- Write the patients name and date on the card and go through the key points with them.
- Further supply of patient [cards](#) can be ordered as detailed on page 1.

Off - label use: risks and advice still apply

Valproate is not licensed for treatment of conditions other than epilepsy or bipolar disorder in the UK. It is used off label for migraine and is an amber traffic light in the Tayside Area Formulary. Valproate should not be used for migraine prophylaxis in girls or female patients of childbearing potential unless the patient has not responded adequately or tolerated other available treatments. The same risks and advice apply and the resources as outlined above should be used.

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Do you already have a suitable topic for a Tayside Prescriber?

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