

## FAO: Primary Care colleagues in North Yorkshire and York

# Medicines Management Prescribing Focus – October 2024

## Valproate Use in Men

In September the MHRA issued [new guidance for the use of valproate in men](#) with the following advice for healthcare professionals:

- inform male patients (of any age) who may father children of the possible risk at initiation of valproate or at their next regular treatment review – this counselling should be given irrespective of the indication for valproate and also after intravenous use of valproate
- as a precaution, recommend that male patients use effective contraception (condoms, plus contraception used by the female sexual partner) throughout the valproate treatment period and for 3 months after stopping valproate, to allow for one completed sperm cycle not exposed to valproate
- at the next regular treatment review, discuss with men on oral valproate treatment whether they are planning a family in the next year and if they are, refer to a specialist to discuss alternative treatment options
- if a female patient reports they are pregnant or planning a pregnancy with a man on valproate (including those undergoing IVF), refer for prenatal counselling
- advise men not to donate sperm during valproate treatment and for 3 months after stopping valproate
- report any suspected adverse drug reactions associated with valproate on a [Yellow Card](#)

### Recommended actions for primary care:

- **at their next regular treatment review inform male patients (of any age) who may father children of the possible risks of valproate, as per the MHRA advice above**
- **as the next treatment review may be some months in the future, we would advise practices to send out the MHRA patient information leaflet to all affected patients as soon as possible: [Advice for male patients on valproate to use contraception](#)**
- **example message: *Dear Patient, you are receiving this important message from your surgery because our records indicate you are being prescribed a medication that requires some new extra precautions to be taken. It is very important you read the advice carefully or ask someone to read it to you if you are unable. Please do not stop taking valproate without discussing it with a healthcare professional. Please contact your GP surgery or hospital team if you have any questions.***
- **this advice should be clearly documented in the clinical record. There is no specific code for this, so for existing valproate patients a non-specific SNOMED code is appropriate along with a free text annotation of ‘valproate’ and ‘Risk of Neurodevelopmental Disorder’: 396080005 Medication side effects education**

## Further resources and support:

NHS England has produced the following documents to support GP practices in discussions with patients regarding the paternal risk of neurodevelopmental disorders (NHS Futures log-on required):

- [FAQ document](#) for general practice
- [Flow chart](#) describing the proposed pathway

The MHRA encourages patients to attend their next routine appointment to discuss their treatment plan and to talk to a healthcare professional if they have any questions.

*No one should stop taking valproate without advice from a specialist because of the importance of keeping their condition under control.*

This new advice comes in addition to measures introduced at the start of this year which stated that from [January 2024](#) valproate must not be started in new patients (male or female) younger than 55 years unless two specialists independently consider and document that there is no other effective or tolerated treatment, or unless there are compelling reasons that the reproductive risks do not apply.

There is now a specific [male risk acknowledgement form](#) which is designed to be completed by the specialists in conjunction with this cohort of men when valproate is started. A copy of the form should be shared with both the patient (or their responsible person) and the GP practice.

Please share the information in this document with all relevant members of staff in the practice.

For any queries or feedback on this topic please contact our team via: [hnyicb-ny.rxline@nhs.net](mailto:hnyicb-ny.rxline@nhs.net)

The MMT welcomes further ideas and suggestions that you and colleagues may wish to recommend for future prescribing focus editions.

Many thanks,

**North Yorkshire and York Medicines Management Team**