Medicines & Healthcare products Regulatory Agency

Risk minimisation measures required for Valproate prescribing

The patient is male and less than 55 years old

Valproate may potentially cause male infertility in patients and neurodevelopmental disorders in children born to men treated with valproate in the 3 months before conception

The reproductive risks apply

Patients should be informed about the reproductive risks

As a precaution men, and their female partners, should be advised to use effective contraception during valproate treatment

The reproductive risks do not apply

The reason should be recorded in the male initiation form, valproate can be prescribed in accordance with standard clinical practice by a single prescriber

No additional action required to minimise this risk

Newly starting valproate

Two specialists must independently consider and document that there is no other effective or tolerated treatment

Complete Risk Acknowledgement Form for male patients

The Risk Acknowledgement Form does **not** need to be completed annually

Currently receiving valproate

Valproate can continue to be prescribed in accordance with standard clinical practice by a single prescriber

Second specialist review is **not** required

Male Risk Acknowledgement form does **not** need to be completed

Key: Decision point — Advice — Risk minimisation activity