Medicines & Healthcare products Regulatory Agency

Risk minimisation measures required for Valproate prescribing

The patient is female and less than 55 years old

Valproate can seriously harm an unborn baby when taken by women during pregnancy and may lead to permanent disability in the offspring

The reproductive risks may apply

Newly starting valproate

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

The patient must follow the conditions of the Pregnancy Prevention Programme

Female ARAF* to be completed by the specialist prescriber with the patient and countersigned by a second specialist

Female ARAF* to be completed by a single specialist prescriber and the patient at each annual review while reproductive risk applies

Currently receiving valproate

Previously been reviewed by two specialists either at initiation or annual review

The patient must follow the conditions of the Pregnancy Prevention Programme

Female ARAF* to be completed by a single specialist prescriber and the patient at each subsequent annual review while reproductive risk applies

Never been reviewed by two specialists

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

The patient must follow the conditions of the Pregnancy Prevention Programme

Female ARAF* to be completed by the specialist prescriber with the patient and countersigned by a second specialist

Female ARAF* to be completed by a single specialist prescriber and the patient at each annual review while reproductive risk applies

There is a permanent reason the reproductive risks do not apply

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

Second specialist review is **not** required

Use the ARAF* to document the clinical decision

The ARAF* does **not** need to be completed annually

*Annual Risk Acknowledgement Form

Key: Decision point — Advice — Risk minimisation activity