Anti-Seizure Medicines (Antiepileptics)

MHRA Drug Safety Update | NICE NG217 (2022) | Valproate Pregnancy Prevention Programme

BRAND CONTINUITY

- ☐ Category 1: Always maintain the same brand. Never substitute without prescriber and patient agreement.
- ☐ Category 2: Maintain brand where possible. Discuss any switch with the prescriber first.
- ☐ Category 3: Switching is usually acceptable, but consider individual patient factors.
- ☐ If the prescription does not specify a brand, follow usual practice and record what was supplied.

Brand continuity guidance mainly applies to epilepsy treatment.

MHRA Brand Categories at a Glance

Category	Brand Policy	Key Drugs
1: Always maintain	Never switch without agreement	Phenytoin, Carbamazepine, Phenobarbital, Primidone
2: Maintain where possible	Discuss switch with prescriber	Valproate, Lamotrigine, Topiramate, Oxcarbazepine, Clobazam, Clonazepam, Zonisamide, Perampanel, Eslicarbazepine, Rufinamide
3: Usually flexible	Switching generally acceptable	Levetiracetam, Lacosamide, Gabapentin, Pregabalin, Ethosuximide

⚠ VALPROATE REQUIREMENTS

- ☐ Supply sodium valproate in the original manufacturer's full pack. Do not repackage except in exceptional circumstances supported by an individual risk assessment.
- ☐ Confirm patient card and Patient Information Leaflet are present.
- ☐ Women and girls of childbearing potential: Pregnancy Prevention Programme must be in place. Annual Risk Acknowledgement Form should be completed and current.
- ☐ Valproate initiation requires specialist confirmation that Pregnancy Prevention Programme requirements are met.
- ☐ MHRA advises effective contraception for men taking valproate and their partners.

⚠ REPEAT DISPENSE CHECKS

- ☐ Confirm the brand and manufacturer match previous supplies. Record what was dispensed every time.
- ☐ Drug shortage: check the SPS Medicines Supply Tool. Contact the prescriber before switching Category 1 or Category 2 medicines.
- ☐ Ask: "Have you had any new or more frequent seizures since your last supply?"
- ☐ Ask valproate patients of childbearing potential: "Are you pregnant, planning a pregnancy, or could you become pregnant?"

RED FLAGS: ACT IMMEDIATELY

- ☐ Seizure lasting more than 5 minutes, or repeated seizures without recovery: call 999.
- ☐ New or increased seizure frequency after any brand or dose change: urgent prescriber review.
- ☐ Rash with carbamazepine or lamotrigine (especially widespread, blistering, with fever, mouth ulcers, eye involvement, or skin peeling): stop the medicine and attend A&E immediately.
- ☐ Valproate toxicity (confusion, unsteadiness, drowsiness, vomiting, tremor): urgent medical assessment.
- ☐ Phenytoin toxicity (double vision, slurred speech, involuntary eye movements, unsteady gait): urgent medical assessment.
- ☐ Valproate patient reports pregnancy or possible pregnancy: refer urgently to the specialist team. Do not stop treatment suddenly unless advised by the specialist.

Key reminders: Never stop anti-seizure medicines suddenly; abrupt withdrawal can trigger status epilepticus. Carbamazepine: screen Han Chinese and Thai patients for HLA-B*1502 before starting (Stevens-Johnson syndrome risk). Enzyme-inducing medicines (carbamazepine, phenytoin, phenobarbital) can reduce the effectiveness of hormonal contraceptives. Any change in seizure control may affect driving entitlement.