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| **INFORMATION SHEET – Blue Traffic Light Classification** | |
| **Name of medicine** | Sodium valproate |
| **Indication**  **(including whether for adults and/or children)** | Epilepsy in men and in females who are **not** of childbearing potential |

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| **PCN policy statement reference**  **(if applicable)** | | PCN 381-2018 | |
| **Author(s):** Alison Marshall, Lead Pharmacist, Quality & Governance  **Organisation(s):** Surrey & Borders Partnership NHS Foundation Trust | | | |
| **Version:V3** | **PCN recommendation date: 12/2018** | | **Review date: December 2021** |

The information sheet is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface for medicines classified by Prescribing Clinical Network as **BLUE**

**BLUE** drugs are considered suitable for prescribing in primary care, following initiation and stabilisation by a specialist as ongoing monitoring can be undertaken in primary care without specialist support and WITHOUT the need for a formal shared care guideline.

For each drug classified as blue, the Prescribing Clinical Network will recommend the minimum supply and whether an information sheet is required or not. A minimum of one month supply of medication will be provided by the initiating consultant.

This information sheet sets out the patient pathway relating to this medicine and any information not available in the British National Formulary and manufacturer’s Summary of Product Characteristics. Prescribing must be carried out with reference to those publications. A GP or Primary Care Prescriber must ensure they are familiar with the prescribing responsibilities. This information sheet is available on the internet [**http://pad.res360.net/**](http://pad.res360.net/) forming part of the Prescribing Advisory Database (PAD) giving GPs appropriate advice / guidance and is not required to be sent to the GP with the clinic letter.

**RESPONSIBILITIES and ROLES**

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| **Consultant responsibilities** |
| 1. To assess the suitability of patient for treatment |
| 1. To discuss the aims, benefits and side effects of treatment with the patient and/or carer as well as their role |
| 1. Explain to the patient and/or carer the treatment plan including the dosing schedule and request for transfer of care to GP |
| 1. Baseline monitoring undertaken |
| 1. Monitor and evaluate response to treatment, including adverse drug reactions, with the patient and to continue / discontinue treatment in line with agreed treatment plan |
| 1. Supply GP with summary of patient review (including anticipated length of treatment) and a copy of any information sheet available |
| 1. Advise GP if treatment is to discontinue at any point |
| 1. Inform GP if patient does not attend planned follow-up |
| 1. To prescribe a minimum of one month’s treatment of valproate |
| 1. Dose titration according to the manufacturer’s Summary of Product Characteristics, and the person’s response to treatment |
| 1. Pre-treatment monitoring required:   LFTs, FBC (including platelet count, bleeding time and coagulation tests) and BMI/weight. TFT if new diagnosis or clinical concerns. |
| 1. Monitoring during stabilisation: Periodic monitoring of LFTs during the first 6 months until patient is stabilised. The frequency may need to be determined on a patient by patient basis |
| 1. At 6 months after initiation   FBC, LFTs, Weight/ BMI |

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| **General Practitioner (GP) or Primary Care Prescriber responsibilities** |
| 1. Subsequent prescribing of sodium valproate at the dose recommended |
| 1. Maintenance treatment monitoring   **Annually:**  LFTs, FBC and BMI |
| 1. Adjust the dose as advised by the specialist |
| 1. Contact the specialist if you suspect the patient is not complying with their medication |
| 1. Check for possible drug interactions when prescribing new medication and avoid prescribing interacting drugs |
| 1. Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises |
| 1. Refer the patient to the specialist if his/her condition deteriorates |
| **Patient / Carer role** |
| 1. Informing the specialist team, primary care prescriber or other healthcare professional if he or she has further questions or wants more information about the treatment |
| 1. Tell the consultant / specialist or GP or Primary Care Prescriber of any other medication being taken, including over-the-counter products. |
| 1. Sharing any concerns about their treatment and problems they are having taking their medicines with the specialist team, primary care prescriber or other healthcare professional involved in their care |
| 1. Supported to know how to report any adverse effects to the specialist team, primary care prescriber or other healthcare professional involved in their care, and how adverse effects can be managed |
| 1. To be available for monitoring as required |
| 1. Attend follow-up appointments with the consultant / specialist / GP. **Non-attendance of appointments may result in treatment being stopped** |

**Key information on the medicine**

Please refer to the current edition of the British National Formulary (BNF), available at https://bnf.nice.org.uk/, and Summary of Product Characteristics (SPC), available at [www.medicines.org.uk](http://www.medicines.org.uk) for detailed product and prescribing information and specific guidance.

**Background to disease and use of medicine for the given indication**

NICE guidance was published in 2012, and updated in 2018 on the topic of the diagnosis and management of epilepsies (Clinical Guideline 137). The guideline covers diagnosing, treating and managing epilepsy and seizures in children, young people and adults in primary and secondary care. It offers best practice advice on managing epilepsy to improve health outcomes so that people with epilepsy can fully participate in daily life. Specific treatment recommendations are given for each individual seizure type.

**Indication**

Sodium valproate is licensed for the treatment of all forms of epilepsy.

**Dosage and Administration**

Refer to current Summary of Product Characteristics (SPC): [www.medicines.org.uk](http://www.medicines.org.uk) and other specialist guidelines.

**Expected outcome**

To treat epilepsy and to prevent recurrence of seizures

**Monitoring**

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| Test | Frequency | Abnormal Result | Action if Abnormal Result |
| FBC | Pre treatment, 6 months after initiation and every 12 months thereafter | Outside normal range | Consider alternative explanations  Refer to specialist  Monitor until returned to normal |
| LFTs | Pre treatment, periodically during the first 6 months until patient stabilised, 6 months after initiation and every 12 months thereafter | Outside normal range | Consider alternative explanations  Refer to specialist  Monitor until returned to normal |
| Weight / BMI | Pre-treatment, 6 months after initiation and every 12 months thereafter | Significant upward trend | 1. Discuss lifestyle choices, weight management, diet and exercise. |

**Cautions, contraindications -** Refer to current Summary of Product Characteristics (SPC): [www.medicines.org.uk](http://www.medicines.org.uk)

**Adverse effects -** Refer to current Summary of Product Characteristics (SPC): [www.medicines.org.uk](http://www.medicines.org.uk)

**Drug interactions -** Refer to current Summary of Product Characteristics (SPC): [www.medicines.org.uk](http://www.medicines.org.uk)