

# DRUG SAFETY NOTICE

## Supply Shortage

### DRUG NAME/STRENGTH/Form:

**Phenytoin 250mg in 5ml Solution for Injection Ampoules**

### **PROBLEM**

- Phenytoin 250mg in 5ml Solution for Injection Ampoules are unavailable from suppliers
- Anticipated re-supply date is TBC later in September 2024

### **ACTION**

- Ensure remaining supplies are preserved for use in priority indications and clinical areas e.g. in epilepsy or status epilepticus.
- In non-priority clinical indications, review and consider the alternatives below

### **ALTERNATIVES**

The choice of alternative parenteral agent should be made by the clinician and guided by individual patient needs.

The following alternative parenteral anti-seizure medications can support a full uplift in demand:

- **Levetiracetam 500mg/5ml concentrate for solution for infusion vials**
- **Sodium valproate 300mg/1ml solution for injection ampoules**

The following alternative parenteral anti-seizure medications **cannot** support any uplift in demand:

- Phenobarbital 30mg/1ml, 60mg/1ml and 200mg/ml solution for injection vials
- Lacosamide 20mg/20ml solution for infusion vials (off-formulary)
- Fosphenytoin (Pro-Epanutin) 750mg/10ml concentrate for solution for injection vials (off-formulary)
- Brivaracetam (Briviact) 10 mg/ml solution for injection/infusion

### **SUPPORTING INFORMATION**

Phenytoin Injection is licensed for the control of status epilepticus of the tonic-clonic (grand mal) type and prevention and treatment of seizures occurring during or following neurosurgery and/or severe head injury.

[NICE guidance](#) recommends that if convulsive status epilepticus does not respond to 2 doses of a benzodiazepine, any of the following medicines should be given intravenously as a second-line treatment: levetiracetam, phenytoin, or sodium valproate.

***NOTE: As valproate therapy is frequently associated with risk of teratogenicity, it is contraindicated during pregnancy unless there is no suitable alternative to treat epilepsy. Valproate administration may also impair fertility in men. These risks should be considered and balanced against the risk of uncontrolled status epilepticus.***

Phenytoin intravenous infusions is also on the Trust Formulary for the off-label use in the management of **acute severe trigeminal neuralgia**. It is a treatment option suggested in the Royal College of Surgeons, England [guidelines](#) on trigeminal neuralgia, should adjuvant acute treatments be ineffective, for inpatient treatment of acute relapses (administered only by specialists).

### Key Resources

[SPC: Phenytoin injection](#)

[SPC: Levetiracetam infusion](#)

[SPC: Sodium valproate solution for injection/infusion](#)

[NICE guideline \[NG217\]: Epilepsies in children, young people and adults](#)

[Royal College of Surgeons, England. Guidelines for the management of trigeminal neuralgia, 2021](#)

[MHRA: Valproate use by women and girls](#)

FOR FURTHER INFORMATION CONTACT YOUR WARD BASED PHARMACY TEAM  
OR  
THE PHARMACY DEPARTMENT (CITY ext.5263; SANDWELL ext.3783).

DATE OF ISSUE: 09.09.2024

REFERENCE NUMBER: 02-0924