



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

**THERAPEUTIC GOODS ACT 1989, S.19(1)(a) EXEMPTIONS FOR SPECIAL AND EXPERIMENTAL USES  
APPROVAL TO SUPPLY UNDER THE SPECIAL ACCESS SCHEME**

**Drug:** Sodium Phenylbutyrate

**Dosage Regimen:** 250 mg/kg, intravenously by infusion over 2-3 hours

**Duration:** 12 Months

**Dose Form:** solution

Yours sincerely,

Signed and authorised by  
Dr Christine Frost  
Delegate of the Secretary  
Prescription Medicines Authorisation Branch  
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