

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: as per protocol, intravenously (for use in emergency / loading dose)

Duration: 12 Months Dose Form: injection

Yours sincerely,

Signed and authorised by Dr Rhianna Thompson Delegate of the Secretary Prescription Medicines Authorisation Branch Email:sas@tga.gov.au

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