Australian Government

Department of Health

Therapeutic Goods Administration

[redacted]

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

[redacted]

Dosage Regimen: As per protocol - rapid infusion: 250 mg/kg by intravenous infusion over 2-3 hours, maintenance infusion 250 mg/kg/day by intravenous infusion, when required for acute hyperammonaemia

Duration: 12 Months

Dose Form: injection

[redacted]

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Yours sincerely,

Signed and authorised by
Dr Kaye Robertson
Delegate of the Secretary
Prescription Medicines Authorisation Branch
Email:sas@tga.gov.au
14-June-2017