



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: 3 . 5 grams three times daily

Duration: 12 Months

Dose Form: tablet

Yours sincerely,

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