



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: 4 grams four times daily, orally

Duration: 12 Months

Dose Form: tablet

Yours sincerely,

Signed and authorised by
Dr Christine Frost
Delegate of the Secretary
Prescription Medicines Authorisation Branch
Email: sas@tga.gov.au
05-May-2017