



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: 350mg three times daily

Duration: 12 Months

Dose Form: oral liquid

Yours sincerely,

Signed and authorised by
Andrew Leaver
Delegate of the Secretary
Prescription Medicines Authorisation Branch
Email: sas@tga.gov.au
10-July-2017