Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <http://www.tga.gov.au/about/tga-information-to.htm>.

Category B form Special Access Scheme

Please complete clearly and in full - forms cannot be processed if incomplete or illegible

Do not provide the name of the patient. Only provide the patient's initials and other information as requested on this form.
Email completed form to SAS@tga.gov.au (preferred) or fax to 02 6232 8112.

Privacy information

For general privacy information, go to <http://www.tga.gov.au/about/website-privacy.htm>.

The TGA is collecting personal information in this form in order to:

- Assess the application.
- Contact the medical practitioner and discuss the application where necessary.
- The personal information of the medical practitioner may be disclosed to State and Territory authorities with responsibility for therapeutic goods or medical practitioner registration.

Patient details (minimum of 3 (three) identifiers required)

[redacted]

Diagnosis	citrullinaemia	Previous SAS No.(if applicable)	
Clinical justification for use of product. For example - Include seriousness of condition, details of previous treatment	Life saving therapy		

Product details *Attach efficacy and safety data to support proposed use of the product and details of intended monitoring. Note: Boxes marked with an * must be completed for devices.*

Active ingredient	Sodium Phenylbutyrate	Trade name/device name*	
Company/supplier*		Route of administration	gastrostomy button
Dose form & strength (e.g. 500mg tablet)	100m/mL(10%)Solut	Proposed treatment duration	12 months and ongoing
Dose & frequency* (e.g. 1 tds)	3.5mLs TDS (350mgs)		
Intended date of use*	ongoing	Proposed quantity*	1 month supply

[redacted]

SAS Category B