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	Hyperammonaemia	Previous SAS No.(if applicable)	N/A.
Clinical justification for use of product. For example - include seriousness of condition, details of previous treatment	Life threatening metabolic condition. Requires treatment to sustain life.		

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 Benzoate	Trade name/device name*	Sodium Benzoate
Company/supplier*	Dale pharmaceuticals	Route of administration	pō (oral)
Dose form & strength (e.g. 500mg tablet)	500mg tablet	Proposed treatment duration	ongoing.
Dose & frequency* (e.g. 1 tds)	250mg pō TDS.		
Intended date of use*	immediate	Proposed quantity*	100 tablets

Prescriber details

[redacted]