



This form, when completed, will be classified as 'For official use only'.  
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### 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](mailto: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 (maximum of 2 lines of text)

Diagnosis	urea cycle disorder	Previous SAS No. (if applicable)
Clinical justification for use of product. For example - Include seriousness of condition, details of previous treatment	Admission with hyperammonemic encephalopathy. Sodium benzoate binds to amino acids and allow excretion and decrease in ammonia.	

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*	Anzoate
Company/supplier*		Route of administration	oral
Dose form & strength (e.g. 500mg tablet)	100mg tablets	Proposed treatment duration	(12 months) long term
Dose & frequency* (e.g. 1 tabs)	as required twice a day		
Intended date of use*	Ongoing	Proposed quantity*	

#### Prescriber details