



**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](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 (minimum of 3 (three) identifiers required)**



Diagnosis	Argininosuccinic aciduria	Previous SAS No. (if applicable)	
Clinical justification for use of product. For example - include seriousness of condition, details of previous treatment	Argininosuccinic aciduria is a urea cycle disorder. Individuals with this condition are at risk of hyperammonaemia. Sodium benzoate is an ammonia-scavenging medication and is indicated in the management of argininosuccinic aciduria.		

**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*	
Company/supplier*		Route of administration	PO/PEG
Dose form & strength (e.g. 500mg tablet)	500mg tablet	Proposed treatment duration	Lifelong
Dose & frequency* (e.g. 1 tds)	5 grams TDS		
Intended date of use*	Immediately	Proposed quantity*	12 months

**Prescriber details**

