



Category B form Special Access Scheme

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.

PLEASE COMPLETE IN FULL AND CLEARLY – FORMS WILL NOT BE PROCESSED IF INCOMPLETE

Patient details



Diagnosis	Arginosuccinic Aciduria (urea cycle disorder)	Previous SAS No. (if applicable)	
Clinical justification for use of product Include seriousness of condition, details of previous treatment (attach additional pages if necessary)	Serious disorder - potential for death or brain damage with decompensation. Medication helps prevent decompensation and hence admissions and complications		

Product details

Attach efficacy and safety data to support proposed use of the product and details of intended monitoring. **Must be completed for devices.

Active ingredient*	Sodium Benzoate	Trade name/ device name**	Amzoate
Company/supplier**	Special Products Limited		
Dose form*	Tablets	Route of administration*	Oral
Dosage frequency*	750mg TDS	Duration of treatment	12 months
Intended date of use**	13/07/17	Quantity requested	12 months

Prescriber details

