



Australian Government

Department of Health

Therapeutic Goods Administration

Office use only

**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](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.

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

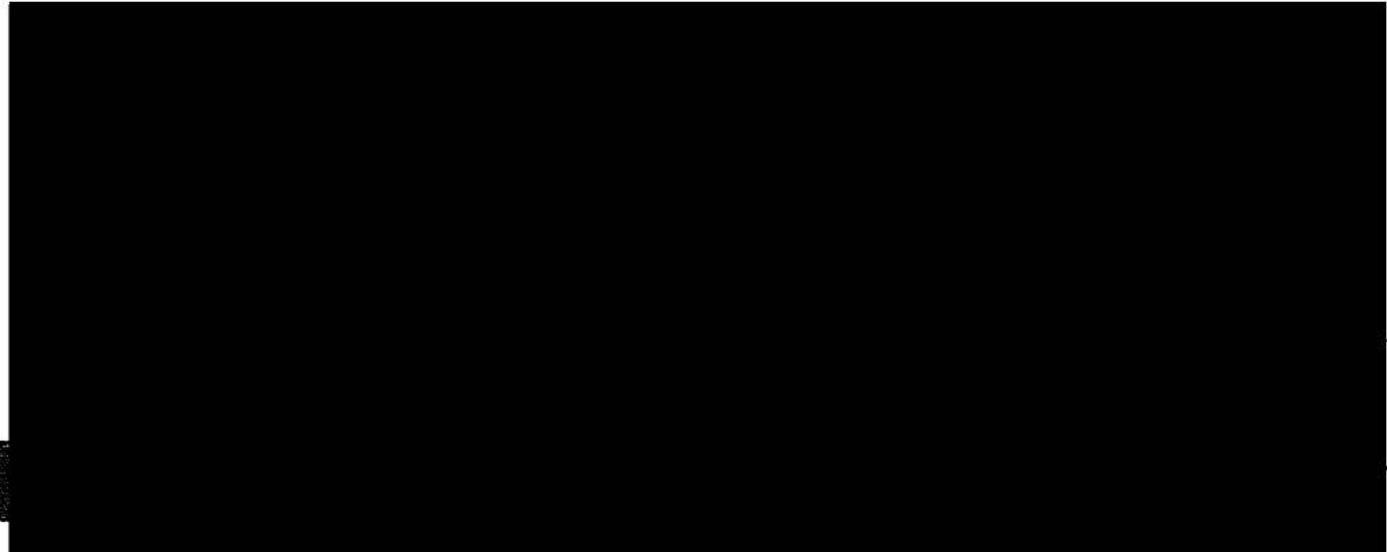
Diagnosis	Citrullinaemia (Argininosuccinate Synthase Deficiency)	Previous SAS No. (if applicable)	2016/13080
Clinical justification for use of product	Sodium benzoate is an ammonia scavenger capable of binding ammonia in a soluble non-toxic form which can then be excreted in the urine.		
Include seriousness of condition, details of previous treatment (attach additional pages if necessary)	If [redacted] does not receive ammonia scavengers, [redacted] can rapidly develop elevated ammonia and encephalopathy which may be fatal.		

**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 2g/10mL	Trade name/ device name**	Amzoate®
Company/supplier**	Medsurge Healthcare		
Dose form*	Ampoule	Route of administration*	IV
Dosage frequency*	As per protocol	Durallon of treatment	Indefinite
Intended date of use**	Ongoing	Quantity requested	12 months supply

**Prescriber details**

			
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