Australian Government
Department of Health
Therapeutic Goods Administration

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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

[redacted]

Diagnosis	Citrullinaemia (Argininosuccinate Synthase Deficiency)	Previous SAS No. (if applicable)	2016/13078
Clinical justification for use of product *Include seriousness of condition, details of previous treatment (attach additional pages if necessary)*	Citrullinaemia is a severe life threatening urea cycle defect. [redacted] was diagnosed in infancy and has required medication to bind his ammonia ever since. Sodium phenylbutyrate is metabolised to sodium phenylacetate which then conjugates with glutamine to form sodium phenylacetylglutamine which is water soluble, and is excreted in the urine.		

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

[redacted]