



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**

Diagnosis	Hyperammonaemia.	Previous SAS No. (if applicable)	2014/06112
Clinical justification for use of product	Orthinine transcarbamylase deficiency.		
Include seriousness of condition, details of previous treatment (attach additional pages if necessary)	████████████████████ has severe OTC deficiency which is a urea cycle defect. █████ has required both phenylbutyrate and benzoate to act as ammonia scavengers. Ammonia scavengers are critical for █████ survival.		

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 4-Phenylbutyrate 250mg/mL	Trade name/ device name**	Ambutyrate®
Company/supplier**	Medsurge Healthcare		
Dose form*	Solution	Route of administration*	Oral
Dosage frequency*	As per protocol	Duration of treatment	Indefinite
Intended date of use**	Ongoing	Quantity requested	12 months