



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	Ornithine transcarbamylase deficiency	Previous SAS No. (if applicable)	2016/11603
Clinical justification for use of product <i>Include seriousness of condition, details of previous treatment (attach additional pages if necessary)</i>	<p>██████ has unstable OTC deficiency which is an in born error of the urea cycle. Sodium Phenylbutyrate is an ammonia scavenger capable of binding ammonia in a soluble non-toxic form which can then be excreted in the urine.</p> <p>If ██████ does not receive ammonia scavengers, she can rapidly develop elevated ammonia and encephalopathy which may be fatal.</p>		

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

Prescriber details

