Australian Government

Department of Health
Therapeutic Goods Administration

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This form, when completed, will be classified as 'For official use only'.
For guidance on how your information will be treated by the TGA see: Treatment of Information provided to the TGA at
<http://www.tga.gov.au/about/tga-information-to.htm>.

Category B form Special Access Scheme

Please complete clearly and in full - forms cannot be processed if incomplete or illegible

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.

Patient details (minimum of 3 (three) identifiers required)

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Diagnosis	ORNITIAING TRANSCARBAMYLASE DEFICIENCY (OTC)	Previous SAS No.(if applicable)	2017/02575
Clinical justification for use of product. For example - include seriousness of condition, details of previous treatment	To prevent Hyper-Ammonaemia, ↓ consciousness coma & death		

Product details   *Attach efficacy and safety data to support proposed use of the product and details of intended monitoring.*
Note: Boxes marked with an * must be completed for devices.

Active ingredient	Sodium Benzoate		Trade name/device name*	
Company/supplier*	Medsurge		Route of administration	Oral
Dose form & strength (e.g. 500mg tablet)	500mg tablet		Proposed treatment duration	12 months
Dose & frequency* (e.g. 1 tds)		2 ö TWICE DAILY.		
Intended date of use*	CURRENT ON 17 INDEFINITE		Proposed quantity*	O ngoing

Prescriber details

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