Document 33

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Australian Government

Department of Health

Therapeutic Goods Administration

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This form, when completed, will be classified as 'For official use only'.
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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)

[redacted]

Diagnosis	↓ Ornithine Transcarbamylase Deficiency	Previous SAS No.(if applicable)	
Clinical justification for use of product. For example - Include seriousness of condition, details of previous treatment	SODIUM BENZOATE 500 mg TABS for ORNITHINE TRANSCARBAMYLASE DEFICIENCY (OTC) to prevent high ammonia & COMA WHILE ON LOW CALORIE DIET prior to BARIATRIC SURGERY. while on low calorie diet prior to bariatric surgery.		

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*		Route of administration	Oral
Dose form & strength (e.g. 500mg tablet)	500mg tablet	Proposed treatment duration	6 months.
Dose & frequency* (e.g. 1 tds)	2 i b.d		
Intended date of use*	13/2/17	Proposed quantity*	

Prescriber details

[redacted]

[redacted]