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	OTC Deficiency	Previous SAS No. (if applicable)	2016/09601
Clinical justification for use of product *Include seriousness of condition, details of previous treatment (attach additional pages if necessary)*	Sodium benzoate is a routinely used medication for the treatment of urea cycle disorders including OTC deficiency.		

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 Benzoate	Trade name/ device name**	Amzoate
Company/supplier**	Special Products Limited		
Dose form*	Tablets	Route of administration*	Oral
Dosage frequency*	500mg mane and middi and 1000mg nocte	Duration of treatment	12 months
Intended date of use**	27/07/2017	Quantity requested	12 months

[redacted]