



Australian Government
 Department of Health
 Therapeutic Goods Administration

Office use only

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	OTC Deficiency	Previous SAS No. (if applicable)	2016/09601
Clinical justification for use of product <i>Include seriousness of condition, details of previous treatment (attach additional pages if necessary)</i>	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