



Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

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)

[Redacted Patient Details]			
Diagnosis	Non-ketotic hyperglycinaemia	Previous-SAS No.(if applicable)	
Clinical justification for use of product. For example - Include seriousness of condition, details of previous treatment	Indicated life-long therapy to reduce hyperglycinaemia. Previous TGA approval for sodium benzoate obtained for [Redacted] now transitioned to care at [Redacted]		

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	PEG
Dose form & strength (e.g. 500mg tablet)	500mg tablet	Proposed treatment duration	Life-long
Dose & frequency* (e.g. 1 tds)	17 grams per day, split over TDS dosing.		
Intended date of use*	23/3/2017	Proposed quantity*	Maximum

Prescriber details

[Redacted Prescriber Details]			
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