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 <https://www.tga.gov.au/treatment-information-provided-tga>.

Special Access Scheme – Category B

Important information

Email completed form to SAS@health.gov.au (preferred) or fax to 02 6232 8112.

The SAS Category B application form should be completed if guidance for use of an unapproved good will be met and the SAS Category A or SAS Category C pathways are not applicable.

Privacy information

For general privacy information, go to <https://www.tga.gov.au/privacy>.

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.

Do not provide the name of the patient. Only provide the patient's initials and other information as requested on this form.

Please complete the form clearly and in full. Applications cannot be assessed if the form is incomplete or illegible. PLEASE PRINT IN BLOCK LETTERS.

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

[redacted]

Diagnosis(es) or Medical Condition(s): Ornithine transcarbamylase deficiency

Indication: Management of hyperammonaemia

Clinical justification for use of product: (e.g. Include seriousness of condition, details of previous treatment including reasons why a therapeutic good currently listed on the ARTG cannot be used for the treatment of this patient in this circumstance)

Life saving drug - without this [redacted] would develop severe hyperammonaemia causing permanent brain injury and/or death

Product details (attach efficacy and safety data to support proposed use of the product and details of intended monitoring)

Therapeutic good type Medicine ☑ Biological ☐ Medical device ☐

Medicine/biological

Trade Name (if known)	**Sponsor / Supplier**
Active ingredient(s) Sodium Benzoate	
Dosage form (e.g. tablet) liquid	**Strength** (e.g., 1 mg/ml) 200mg/mL
Route of administration (e.g., IV) oral	**Dose & frequency** (1 tds) 16mL (= 3.2g) QID
Quantity[1] **required for treatment or duration** 12 months	

Medical device

Trade name	
Product description (including variant[2]**)**	
No of units	**Sponsor / Supplier**
Proposed duration of treatment	**Intended date of use**

[1] For substances captured by the Customs (Prohibited Imports) Regulations 1956 the quantity must be provided
[2] Variant means a medical device the design of which has been varied to accommodate different patient anatomical requirements (for example, relating to the shape, size, length, diameter or gauge of the device)

Treating health practitioner details

Submitter details (if different)

[redacted]

Please send this form to the TGA only

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[i] The health practitioner type is any of the following: Medical practitioner; ATSI health practitioner; dentist; radiographer; nurse; midwife; occupational therapist; optometrist; pharmacist ; podiatrist; psychologist.