



Australian Government
Department of Health
Therapeutic Goods Administration

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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)

| | |
|---|---|
| Diagnosis | OTC Deficiency |
| Clinical justification for use of product | Sodium benzoate is a routinely used medication for treatment of urea cycle disorders including OTC deficiency. <i>(For example, include seriousness of condition, details of previous treatment)</i> |

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* | Amzoate |
| Company/supplier* | Special Products Limited | Route of administration | oral |
| Dose form & strength (e.g. 500mg tablet) | Tablets | Proposed treatment duration | 12 months |
| Dose & frequency*(e.g. 1 tds) | 2g po TDS | | |
| Intended date of use* | 20/12/2017 | Proposed quantity* | 12 months |

Prescriber details