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 (Sep 2020)

Important information

Email completed form to SAS@health.gov.au (preferred) or fax to 02 6203 1105.

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 health practitioner and discuss the application where necessary.
- The personal information of the health 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, in full and sign. Applications cannot be assessed if the form is incomplete or illegible. TYPE OR PRINT IN BLOCK LETTERS.

Patient details (do not provide the patient's name – provide at least three patient identifiers)

Patient initials	**Gender** Male ☐ Female ☐ Intersex/Indeterminate/Unspecified ☐	**DOB**	**MRN** (if applicable)
Diagnosis(es)			**Previous SAS No.** (if applicable)
Indication			
Clinical justification for use of product(e.g. outline of the patient's symptoms and/or diagnosis, details of relevant past treatments and procedures trialled or considered, reasons why therapeutic goods currently included in the ARTG may not be the most appropriate treatment for the individual patient in the particular circumstance, an appraisal of the expected clinical benefits versus the potential risks – DO NOT LEAVE BLANK)			

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

Medicine ☐ Biological ☐

Trade Name (if known)	**Sponsor / Supplier**
Active ingredient(s)	
Dosage form (e.g. tablet)	**Strength** (e.g., 1 mg/ml)
Route of administration (e.g., IV)	**Dose & frequency** (1 tds)
Expected duration of treatment	

Medical device

Trade name	
Product description (including variant[1])	
No of units to be supplied	**Sponsor / Supplier**
Expected duration of treatment	**Intended date of use**

[1] 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)

Prescribing health practitioner details

First name	**Surname**
AHPRA ID	**Health practitioner[i] type**
Email	**Speciality**
Fax	**Phone**
Principal practice address	

Submitter details (if different)

Business or practice name	**AHPRA ID**
First name (as per AHPRA registration)	**Surname**
Health practitioner type	**Fax**
Email	**Phone**
Preferred Contact: ☐ Prescribing health practitioner ☐ Submitter	**Preferred contact method:** Email ☐ Fax ☐ Phone ☐

Please note that the giving of false or misleading information is an offence under the *Criminal Code Act 1995* and that penalties may be imposed.	
Submitter's signature	**Date**

Please send this form to the TGA only