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 A

Important information

Please complete clearly and in full

Medicines/biologicals: **Category A** *patient* means a person who is seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment.

Medical devices: **Category A** *patient* means a person who is seriously ill with a condition that is reasonably likely to lead to the person's death within less than a year or, without early treatment, to the person's premature death.

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

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 verify that the criteria for the administration of the medicine were met and to contact the medical practitioner and discuss the circumstances 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 PRINT IN BLOCK LETTERS

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

Patient initials	**Gender:** Male ☐ Female ☐ intersex/indeterminate/unspecified ☐	**DOB**
Diagnosis		
Indication		

Product details

Therapeutic good type Medicine ☐ Biological ☐ Medical device ☐

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 quantity[1] **required for treatment and/or duration**	
Intended date of supply	

Medical device

Trade name	
Product description (including variant[2])	
No of units to be supplied	**Sponsor / Supplier**
Expected duration of treatment	

Medical practitioner certification

First name	**Surname**	**Email** (preferred)	
Practice address		**Phone**	**Fax**

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

Medical practitioner's signature	**Date**

Please send a copy of this form to the TGA and to the Sponsor/Supplier

[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)