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 (Sep 2020)

Important information

Please complete clearly, in full and sign. TYPE OR PRINT IN BLOCK LETTERS

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 6203 1105.

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 therapeutic good(s) 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 health practitioner registration.

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			

Product details

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	

Medical Practitioner Details

First name	**Surname**
AHPRA ID	**Speciality**
Email	
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: ☐ Medical 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 of supply**

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

[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)