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 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 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)

| **Gender** Male ☐ Female ☐ Intersex/Indeterminate/Unspecified ☐ | **Patient initials** | **DOB** | **MRN** (if applicable) | **Previous SAS No.** (if applicable) |
|---|---|---|---|---|
| **Diagnosis(es) or Medical Condition(s):** | | | | |
| **Indication:** | | | | |
| **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) | | | | |

## 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)** | |
| **Dosage form** (e.g. tablet) | **Strength** (e.g., 1 mg/ml) |
| **Route of administration** (e.g., IV) | **Dose & frequency** (1 tds) |
| **Quantity[1] required for treatment or duration** | |

### 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

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

## Submitter details (if different)

| | |
|---|---|
| **Business or practice name** (e.g. Pharmacy name) | |
| **First name** | **Surname** |
| **Health practitioner type** | **Fax** |
| **Email** | **Phone** |
| **Preferred Contact:**<br>☐ Treating health practitioner<br>☐ Submitter | **Preferred contact method:**<br>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**

[i] The health practitioner type for the **treating health practitioner** details above can be any of the following: Medical practitioner; ATSI health practitioner; dentist; radiographer; nurse; midwife; occupational therapist; optometrist; pharmacist; podiatrist; psychologist. **Other health practitioner types can be included as the submitter**.