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| Therapeutic Goods Administration  |  |
|  | TGA use only |  |
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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

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| Important informationEmail 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 informationFor 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 health 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 (do not provide the patient’s name)

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| --- | --- | --- | --- |
| **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. 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)

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| Medicine [ ]  Biological [ ]

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| --- | --- |
| **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

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

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| Prescribing health practitioner details

|  |  |
| --- | --- |
| **First name**      | **Surname**      |
| **AHPRA ID**      | **Health practitioner**[[2]](#endnote-1) **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 [ ]  |

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| **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**

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) [↑](#footnote-ref-1)
2. [↑](#endnote-ref-1)