



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 <http://www.tga.gov.au/about/tga-information-to.htm>.

Category A form Special Access Scheme

Please complete clearly and in full

Category A patients are defined in the legislation as "persons who are 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".

Do not provide the name of the patient. Only provide the patient's initials and other information as requested on this form.

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

Privacy information

- For general privacy information, go to <http://www.tga.gov.au/about/website-privacy.htm>.
- 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.

Patient and product details

| | | | |
|--|--|---------------------------|--|
| Patient details (initials AND one of either DOB, age, gender or MRN) | | | |
| Diagnosis | | | |
| Name of medicine/device/biological | | | |
| Product form (e.g. tablet, vial) | | Strength (i.e. mg, mg/mL) | |
| Route of administration (e.g. oral, IV) | | Dosage (e.g. 1 tds) | |
| Quantity supplied | | | |
| Company/supplier | | | |

Medical practitioner certification

This completed document constitutes the legal authority for an Australian sponsor to supply the specified product and should be forwarded to the Australian Sponsor of the product, accompanied by a prescription where necessary.

I, the undersigned, a registered medical practitioner in Australia, certify that:

- In my opinion the patient above is a Category A patient as defined in regulation 12A of the Therapeutic Goods Regulations 1990 /regulation 7.2 of the Therapeutic Goods (Medical Devices) Regulations 2002 (delete as appropriate);
- I am prepared to prescribe the medicine/medical device/biological requested; and
- I have obtained the informed consent of the patient, or the patient's legal representative, to the proposed treatment.

| | | | |
|--------------------------|--|-------|--|
| Name (initial & surname) | | Phone | |
| Postal address | | Fax | |
| | | Email | |

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

| | | | |
|----------------------|--|------|--|
| Prescriber signature | | Date | |
|----------------------|--|------|--|