



## CATEGORY A FORM SPECIAL ACCESS SCHEME

**READ CAREFULLY BEFORE COMPLETING**

**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.**

**A copy of the form must be forwarded to the TGA within 28 days of its completion.**

Send to: Medical Officer - SAS, TGA, PO BOX 100, WODEN ACT 2606 [Fax No: (02) 6232 8112]

The basis for these SAS arrangements is that responsibility for prescribing an unapproved therapeutic good appropriately rests with the patient's medical practitioner and the patient. 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". Under s31A(2) and 41JD of the *Therapeutic Goods Act 1989* (the Act) the TGA may seek clarification of the Category A classification of patients. In addition, under s61(3A) of the Act the TGA may release details of inappropriate supply and/or use of unapproved medicines and medical devices to State and Territory authorities. **If you intend to import this product, be aware that an import permit may be required for Customs purposes. Details of goods for which a permit is required may be found at [www.tga.gov.au](http://www.tga.gov.au).**

**PATIENT AND PRODUCT DETAILS - COMPLETE ALL RELEVANT SECTIONS AND PRINT CLEARLY**

PATIENT DETAILS:  
(initials/age or DOB,  
sex)

DIAGNOSIS:

MEDICINE/DEVICE:

DOSAGE/PRODUCT FORM:

STRENGTH:

ROUTE/METHOD OF ADMINISTRATION:

DOSAGE:

DURATION OF TREATMENT:

QUANTITY TO BE SUPPLIED:

AUSTRALIAN SPONSOR OF PRODUCT:

NAME AND ADDRESS FOR SUPPLY OF PRODUCT (HOSPITAL, PHARMACIST OR DOCTOR):

  


**MEDICAL PRACTITIONER CERTIFICATION - COMPLETE ALL SECTIONS AND PRINT CLEARLY**

I, the undersigned, a registered medical practitioner in a State/Territory of 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 requested; and
- I have obtained the informed consent of the patient, or the patient's legal representative, to the proposed treatment.

NAME:

SIGNATURE:

PHONE:

DATE / /

ADDRESS: