Adalimumab
Humira Inj.

TGA THERAPEUTIC GOODS ADMINISTRATION

CATEGORY A FORM
SPECIAL ACCESS SCHEME

Commonwealth Department of Health and Aged Care

3

READ CAREFULLY BEFORE COMPLETING

This completed document constitutes the legal authority for an Australian sponsor to supply the specified drug and should be forwarded to the Australian Sponsor of the Drug, 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 *Therapeutic Goods Regulations, 1991* 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) 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.health.gov.au/tga.**

PATIENT AND PRODUCT DETAILS - COMPLETE ALL SECTIONS AND PRINT CLEARLY

PATIENT DETAILS: (Name and Address) [redacted]

DIAGNOSIS: Microscopic Polyarteritis

MEDICINE/DEVICE: Humira

DOSAGE FORM: 40mg Injection STRENGTH: 40mg/

ROUTE OF ADMINISTRATION: S/C DOSAGE: 40mg

DURATION OF TREATMENT: 6 months (ongoing if response).

QUANTITY TO BE SUPPLIED: 13 Syringes.

AUSTRALIAN SPONSOR OF PRODUCT: [redacted]

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

[redacted]

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 defin[redacted] *Regulations 1989*;
- I am prepared to prescribe the medicine/medical device requeste[redacted]
- I have obtained the informed consent of the patient, or the patien[redacted] proposed treatment.

NAME: [redacted] SIGNATURE: [redacted] DATE 31/5/05

PHONE: [redacted]

ADDRESS: [redacted] Vic [redacted]

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PATIENT AND PRODUCT DETAILS - COMPLETE ALL SECTIONS AND PRINT CLEARLY

PATIENT DETAILS: (Name and Address) [redacted]

DIAGNOSIS: FISTULIZING CROHN'S DISEASE

MEDICINE/DEVICE: ADALIMUMAB. Humira

DOSAGE FORM: 40mg Vial/Syringe STRENGTH: 40 mg in 0·8ml

ROUTE OF ADMINISTRATION: SC INJ DOSAGE: 40mg 2nd weekly

DURATION OF TREATMENT: [redacted] 12 MONTHS.

QUANTITY TO BE SUPPLIED: 3 DOSES.

AUSTRALIAN SPONSOR OF PRODUCT: [redacted]

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

[redacted] SOUTH BRISBANE [redacted]

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 the *Therapeutic Goods Regulations 1989*;
- 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: [redacted] SIGNATURE: [redacted] DATE 18/10/05

PHONE: [redacted]

ADDRESS: [redacted] SOUTH BRISBANE, [redacted]

TGA THERAPEUTIC GOODS ADMINISTRATION

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PATIENT AND PRODUCT DETAILS - COMPLETE ALL SECTIONS AND PRINT CLEARLY

PATIENT DETAILS: (Name and Address) [redacted]

DIAGNOSIS: Severe Crohn's Disease

MEDICINE/DEVICE: Adalimumab. Humira

DOSAGE FORM: 40mg/0.8ml vial STRENGTH: 40mg/0.8ml

ROUTE OF ADMINISTRATION: SC DOSAGE: 40mg 2nd weekly

DURATION OF TREATMENT: 12 months.

QUANTITY TO BE SUPPLIED: 4 Doses

AUSTRALIAN SPONSOR OF PRODUCT: [redacted]

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

[redacted] South Brisbane [redacted]

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 the *Therapeutic Goods Regulations 1989*;
- 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: [redacted] SIGNATURE: [redacted] DATE 12/12/05

PHONE: [redacted]

ADDRESS: [redacted] South Brisbane [redacted]

[redacted]