



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

[REDACTED]
VIC [REDACTED]

SAS No: [REDACTED]
11/04/2013

THERAPEUTIC GOODS ACT 1989, S.19(1) EXEMPTIONS FOR SPECIAL AND EXPERIMENTAL USES
APPROVAL TO SUPPLY UNDER THE SPECIAL ACCESS SCHEME

Drug: Adalimumab
Patient: [REDACTED] **DOB:** [REDACTED] 1992 **Sex:** [REDACTED] **MRN:** [REDACTED]
Dosage Regimen: As per protocol
Duration: Twelve Months
Dose Form: injection

Concerning your application to use the above drug in the treatment of the above patient on the grounds that there is no alternative therapy currently supplied in Australia, I, the medically qualified person named below, hereby provide Notification of Approval. The proposed clinical use of this drug must be regarded both medico-legally and ethically as experimental. No assurance can be given as to the quality, safety and efficacy in the proposed usage. Your co-operation is required concerning sound data management.

Permission is given for the use of the drug in the above patient for the above duration subject to the following conditions:--

1. The doctor and patient, patient's parents or guardian accept responsibility for any adverse consequence of therapy;
2. The product is used within the context of fully informed consent and in accordance with the treatment protocol provided to the TGA with the request.
3. The principles set out in the National Health and Medical Research Council's Statement on Human Experimentation be observed;
4. Details of any suspected adverse drug reactions are to be reported to the Experimental Drugs Section of the Therapeutic Goods Administration ;
5. The Therapeutic Goods Administration be notified of reasons for discontinuation should this occur;
6. Details of patient response to treatment are submitted to the supplier on completion of treatment ensuring compliance with State, Territory and Australian Government privacy legislation.
7. On completion of treatment all remaining supplies of the above product be returned to the supplier or destroyed should no supplier be present in Australia;
8. The person supplying the drug accepts responsibility for any defects in the drug related to the manufacture, distribution or directions for usage including dosage;
9. **Additional Conditions/Comments:** None specified.

This approval must be used within 12 (twelve) months from the date of this letter, or until revoked or until this product is marketed in Australia, whichever occurs first.

[REDACTED]

Delegate of the Secretary
Office of Medicines Authorisation
11/04/2013



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CATEGORY B FORM SPECIAL ACCESS SCHEME
 PLEASE USE BLACK PEN, PRINT CLEARLY AND COMPLETE ALL SECTIONS

Patient details	
Patient's initials: [REDACTED]	DOB: [REDACTED] / 92
MRN: [REDACTED]	SEX: [REDACTED]

Diagnosis	ULCERATIVE COLITIS	Previous SAS No. (if applicable)	[REDACTED]
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Clinical justification for use of product Includes appraisal of seriousness of patient's condition; detail previous treatments and expected benefits from use of the product	RESCUE THERAPY. SEVERE ULCERATIVE COLITIS
	PAN COLITIS.
	RESPONDING TO ADALIMUMAB. ONLY

Product details Attach efficacy and safety data to support proposed use of the product and details of intended monitoring.
 *Complete for medicines and biologicals only.

Active* ingredient	ADALIMUMAB.	Trade name /Device name	HUMERA.
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Company/supplier (State if imported)	ABBOTT.
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Dose form*	injection	Route of administration*	S/C.
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Dosage* (dose x frequency)	100mg 40mg FORTNIGHTLY.	Duration of treatment	12 months.
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Date of medical device/ biological procedure/use	FROM NOW. CONTINUING.
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Prescribing doctor details

Name	[REDACTED]	Hospital	[REDACTED]
Position	[REDACTED]	Department	[REDACTED]

The approval letter will be mailed to this address.

Address	[REDACTED]
Phone	[REDACTED]
Facsimile number	[REDACTED]

Signature & date	[REDACTED] 8/4/13
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