



Australian Government

Department of Health, Disability and Ageing  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

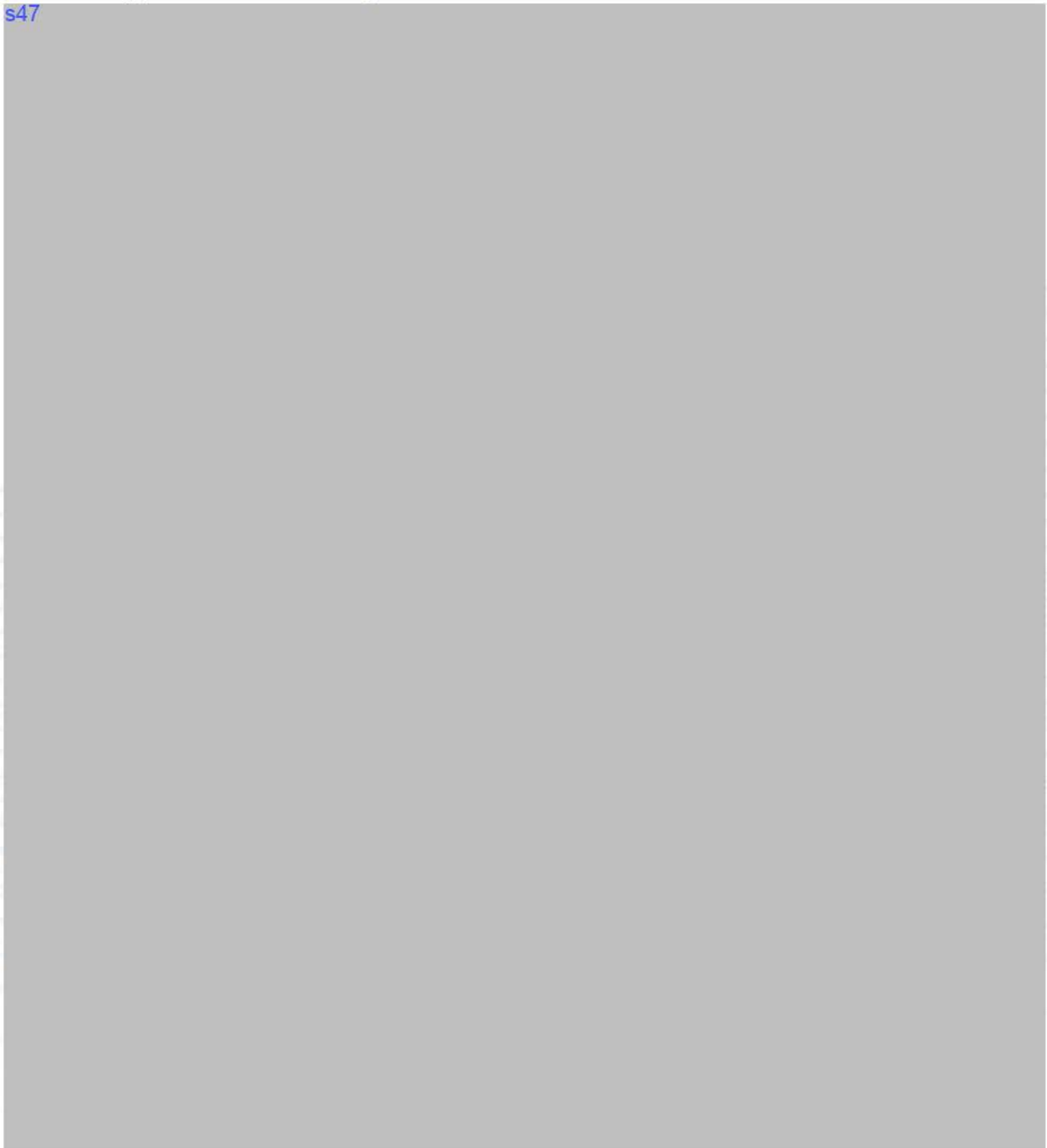
**Bristol-Myers Squibb Australia Pty Ltd**

for approval to supply

**ORENCIA abatacept (rch) 250 mg powder for IV infusion vial**

|                        |                     |
|------------------------|---------------------|
| <b>ARTG Identifier</b> | AUST R 130100       |
| <b>ARTG Start Date</b> | 27/09/2007          |
| <b>Product Type</b>    | Registered Medicine |

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### **ARTG Standard Conditions**

The above Medicine Registered has been entered on the Register subject to the following conditions:

- Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"
- Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 February 1992, other than condition No. 8 and condition No. 9.
- Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 February 1992, other than condition No. 11.
- Except where the sponsor has been contracted by an overseas party to manufacture the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.
- The conditions applying to these goods when they are exported from Australia are given below:
- Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No. 8 and condition No. 9.
- Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No. 11
- Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.
- Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.
- The therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:

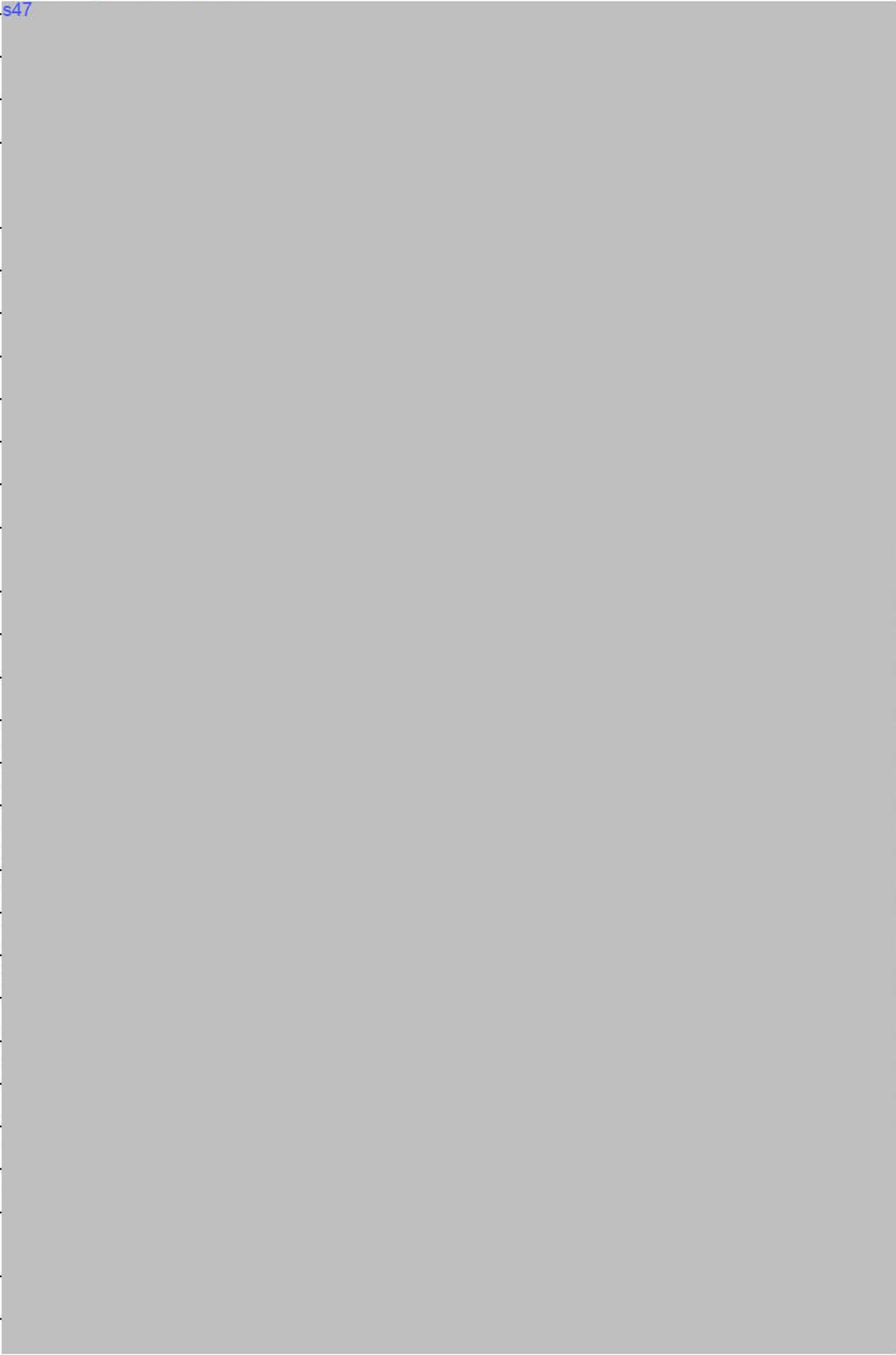
### **Products Covered by This Entry**

1. ORENCIA abatacept (rch) 250 mg powder for IV infusion vial

| Container Type | Container Material | Container Condition | Container Closure | Shelf Life Time | Shelf Life Temperature          | Shelf Life Conditions                        |
|----------------|--------------------|---------------------|-------------------|-----------------|---------------------------------|----------------------------------------------|
| Vial           | Glass Type I Clear | Not recorded        | Not recorded      | 3 Years         | Store at 2 to 8 degrees Celsius | Refrigerate Do not Freeze Protect from Light |

Product Specific Conditions

s47





**Product Permitted Indications**

No permitted indications have been recorded against this entry.

**Product Indication Requirements**

No indication requirements have been recorded against this entry.

**Product Standard Indications**

No standard indications have been recorded against this entry.

**Product Specific Indications**

- ORENCIA in combination with methotrexate is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have had an insufficient response or intolerance to other disease modifying anti-rheumatic drugs (DMARDs), such as methotrexate or tumour necrosis factor (TNF) blocking agents. A reduction in the progression of joint damage and improvement in physical function have been demonstrated during combination treatment with ORENCIA and methotrexate.,ORENCIA in combination with methotrexate is also indicated in the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.,ORENCIA is indicated for reducing signs and symptoms in paediatric patients 6 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). ORENCIA may be used as monotherapy or concomitantly with methotrexate (MTX). (There is no clinical trial data for the use of ORENCIA subcutaneous formulation in children, therefore its use in children cannot be recommended.),ORENCIA is indicated for the treatment of active psoriatic arthritis (PsA) in adults when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. ORENCIA can be used with or without non-biologic DMARDs.,ORENCIA should not be administered concurrently with other biological DMARDs (eg, TNF inhibitors, rituximab, or anakinra).

**Warnings**

See Product Information and Consumer Medicine Information for this product.

**Dosage Form**

- Injection

**Route of Administration**

- Intravenous

**Visual Identification**

- sterile, white, preservative free, lyophilized powder

**Additional Product information**

**Product Formulation(s)**

FOI 27-3601 - Document 1

**Active Ingredients**

|           | Quantity | Units |
|-----------|----------|-------|
| Abatacept | 262.5    | mg    |

Therapeutic Goods Administration  
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ARTG Start Date: 27/09/2007