

Public Summary

Summary for ARTG Entry: 245253 BRENZYS etanercept (rch) 50 mg solution for injection auto-injector

ARTG entry for Medicine Registered
Sponsor ERA Consulting (Australia) Pty Ltd
Postal Address Level 3 / 88 Jephson Street, TOOWONG, QLD, 4066
 Australia
ARTG Start Date 22/07/2016
Product category Medicine
Status Active
Approval area Drug Safety Evaluation Branch

Conditions

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.

Products

1. BRENZYS etanercept (rch) 50 mg solution for injection auto-injector

Product Type	Single Medicine Product	Effective date	22/07/2016
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Warnings

See Product Information and Consumer Medicine Information for this product

Standard Indications

Specific Indications

Adults (18 years and older), Rheumatoid Arthritis, Active, adult rheumatoid arthritis (RA) in patients who have had inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs). Brenzys can be used in combination with methotrexate. Severe, active rheumatoid arthritis in adults to slow progression of disease-associated structural damage in patients at high risk of erosive disease., Psoriatic Arthritis, The signs and symptoms of active and progressive psoriatic arthritis in adults, when the response to previous disease-modifying antirheumatic therapy has been inadequate. Etanercept has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function., Plaque Psoriasis, Adult patients with moderate to severe chronic plaque psoriasis, who are candidates for phototherapy or systemic therapy., Ankylosing Spondylitis, The signs and symptoms of active ankylosing spondylitis in adults., Non-radiographic Axial Spondyloarthritis, Treatment of adults with active* non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or MRI change who have had an inadequate response to NSAIDs .,*Active disease is defined as a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of greater than or equal to 4.

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Syringe	Glass Type I Clear	24 Months	Store at 2 to 8 degrees Celsius	Neither child resistant closure nor restricted flow insert	Refrigerate Do not Freeze

Pack Size/Poison information

Pack Size	Poison Schedule
Pack of 4	(S4) Prescription Only Medicine

Components

1. BRENZYS etanercept (rch) 50 mg solution for injection auto-injector

Dosage Form	Injection, solution
Route of Administration	Subcutaneous
Visual Identification	Auto-injector containing a pre-filled syringe with a clear type I glass barrel, with rubber plunger, stainless steel needle and rubber needle shield

Active Ingredients

Etanercept	50 mg
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