Public Summary

Summary for ARTG Entry:	370315 ACTEMRA SC tocilizumab (rch) 162 mg/0.9 mL solution for injection pre-filled syringe
ARTG entry for	Medicine Registered
Sponsor	Roche Products Pty Ltd
Postal Address	PO Box 255, DEE WHY, NSW, 2099 Australia
ARTG Start Date	11/11/2021
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 . ACTEMRA SC tocilizumab (rch) 162 mg/0.9 mL solution for injection pre-filled syringe

Product Type	Single Medicine Product	**Effective Date**	17/11/2023

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Rheumatoid Arthritis (IV and SC formulations),Actemra is indicated for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients in combination with methotrexate (MTX) or other non-biological disease-modifying anti-rheumatic drugs (DMARDs) in case of either an inadequate response or intolerance to previous therapy with one or more DMARDs.,Actemra is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients with poor prognostic factors (see section 5.1 Pharmacodynamic Properties, Clinical Trials) in combination with MTX in those not previously treated with MTX.,In the two groups of patients above, Actemra can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.,Actemra has been shown to inhibit the progression of joint damage in adults, as measured by X-ray, when given in combination with methotrexate.,Giant Cell Arteritis (SC formulations only),Actemra is indicated for the treatment of giant cell arteritis (GCA) in adult patients.,Polyarticular Juvenile Idiopathic Arthritis (IV and SC formulations),Actemra is indicated for the treatment of moderate to severe active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older who have had an inadequate response to or intolerance to methotrexate (MTX). Actemra can be given alone or in combination with MTX.,Systemic Juvenile Idiopathic Arthritis (IV and SC formulations),Intravenous formulation,Actemra is indicated for the treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older.,Subcutaneous formulation,Actemra is indicated for the treatment of active systemic juvenile idiopathic arthritis in patients 1 year of age and older.,Actemra IV and SC can be given alone or in combination with methotrexate (MTX).

Warnings

See Product Information and Consumer Medicine Information for this product

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	Protect from Light Do not Freeze

Pack Size/Poison information

Pack Size	Poison Schedule
1 syringe	(S4) Prescription Only Medicine
4 syringes	(S4) Prescription Only Medicine

Components

1 . ACTEMRA SC tocilizumab (rch) 162 mg/0.9 mL solution for injection pre-filled syringe

Dosage Form	Injection, solution
Route of Administration	Subcutaneous
Visual Identification	Clear to strongly opalescent, colourless to slightly yellowish solution

Active Ingredients	
Tocilizumab	**162 mg**

Other Ingredients (Excipients)

arginine hydrochloride
histidine hydrochloride monohydrate
histidine
methionine
polysorbate 80
water for injections

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