



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	293333	KEVZARA sarilumab (rch) 200 mg (175 mg/mL) solution for injection pre-filled syringe
ARTG entry for	Medicine Registered	
Sponsor	Sanofi-Aventis Australia Pty Ltd	
Postal Address	Locked Bag 2227, NORTH RYDE BC, NSW, 1670 Australia	
ARTG Start Date	14/09/2018	
Product Category	Medicine	
Status	Active	
Approval Area	Drug Safety Evaluation Branch	



Medicine under additional monitoring

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 . KEVZARA sarilumab (rch) 200 mg (175 mg/mL) solution for injection pre-filled syringe

Product Type	Single Medicine Product	Effective Date	21/12/2018
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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

Kezara in combination with non-biological Disease-Modifying Anti-Rheumatic Drugs (DMARDs) or as monotherapy is indicated for the treatment of moderate to severe active Rheumatoid Arthritis in adult patients who have had an inadequate response or intolerance to one or more DMARDs.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

This product is included in the Black Triangle Scheme

Container information

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

Pack Size/Poison information

Pack Size	Poison Schedule
2 (starter pack)	(S4) Prescription Only Medicine
2	(S4) Prescription Only Medicine

Components

1 . KEVZARA sarilumab (rch) 200 mg (175 mg/mL) solution for injection pre-filled syringe

Dosage Form	Injection, solution
Route of Administration	Subcutaneous
Visual Identification	Clear, colorless to pale yellow, preservative-free liquid solution; supplied in a pre-filled syringe.

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Active Ingredients

sarilumab 200 mg

Other Ingredients (Excipients)

arginine hydrochloride
histidine
polysorbate 20
sucrose
water for injections

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