Public Summary

Summary for ARTG Entry:	326188 REMSIMA infliximab 120 mg solution for injection prefilled syringe in auto-injector pen
ARTG entry for	Medicine Registered
Sponsor	Celltrion Healthcare Australia Pty Ltd
Postal Address	Suite 205/ Level 2/ 1 York Street, Sydney, NSW, 2000 Australia
ARTG Start Date	12/11/2020
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 . REMSIMA infliximab 120 mg solution for injection prefilled syringe in auto-injector pen

Product Type Single Medicine Product **Effective Date** 12/11/2020

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 in adults
REMSIMA in combination with methotrexate, is indicated for the reduction of signs and symptoms and prevention of structural joint damage (erosions and joint space narrowing) in:
- patients with active disease despite treatment with methotrexate
- patients with active disease who have not previously received methotrexate.,REMSIMA should be given in combination with methotrexate. Efficacy and safety in Rheumatoid
Arthritis have been demonstrated only in combination with methotrexate.,Ankylosing Spondylitis
REMSIMA is indicated for the reduction of signs and symptoms and improvement in physical function in patients with active disease.,Psoriatic arthritis
REMSIMA is indicated for the treatment of the signs and symptoms, as well as for the improvement in physical function in adult patients with active and progressive psoriatic arthritis who have responded inadequately to disease-modifying anti-rheumatic drug (DMARD) therapy.
REMSIMA may be administered in combination with methotrexate.,Psoriasis
REMSIMA is indicated for the treatment of adult patients with moderate to severe plaque psoriasis for whom phototherapy or conventional systemic treatments have been inadequate or are inappropriate. Safety and efficacy beyond 12 months have not been established.,Crohn's Disease in Adults
REMSIMA is indicated for the treatment of moderate to severe Crohn's disease, to reduce the signs and symptoms and to induce and maintain clinical remission in patients who have an inadequate response to conventional therapies.,Refractory Fistulising Crohn's Disease
REMSIMA is indicated for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients.,Ulcerative colitis in Adults
REMSIMAis indicated for the treatment of moderately severe to severe active ulcerative colitis in patients who have had an inadequate response to conventional therapy.

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	30 Months	Store at 2 to 8 degrees Celsius	Not recorded	Do not Freeze Refrigerate

Pack Size/Poison information

Pack Size	Poison Schedule
1 pre filled syringe in auto-injector pen	(S4) Prescription Only Medicine

Components

1 . REMSIMA infliximab 120 mg solution for injection prefilled syringe in auto-injector pen

Dosage Form	Injection, solution
Route of Administration	Subcutaneous
Visual Identification	Colourless to pale brown, clear to opalescent solution

Active Ingredients

Infliximab	**120 mg**

Other Ingredients (Excipients)

acetic acid
polysorbate 80
sodium acetate trihydrate
sorbitol
water for injections