Public Summary

Summary for ARTG Entry:	285815 TRUXIMA rituximab (rch) 500 mg/ 50 mL concentrate solution for intravenous infusion
ARTG entry for	Medicine Registered
Sponsor	Celltrion Healthcare Australia Pty Ltd
Postal Address	Level 7 / 9 Castlereagh Street, Sydney, NSW, 2000 Australia
ARTG Start Date	16/04/2018
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 . TRUXIMA rituximab (rch) 500 mg/ 50 mL concentrate solution for intravenous infusion

Product Type	Single Medicine Product	**Effective Date**	20/11/2019

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

Non-Hodgkin's Lymphoma
Truxima is indicated for treatment of patients with: -CD20 positive, previously untreated, Stage III/IV follicular, B-cell non-Hodgkin's lymphoma; - CD20 positive, relapsed or refractory low grade or follicular, B-cell non-Hodgkin's lymphoma; - CD20 positive, diffuse large B-cell non-Hodgkin's lymphoma, in combination with chemotherapy.,Chronic Lymphocytic Leukaemia
Truxima is indicated for the treatment of patients with CD20 positive chronic lymphocytic leukaemia (CLL) in combination with chemotherapy.,Rheumatoid Arthritis
Truxima (rituximab) in combination with methotrexate is indicated for the treatment of adult patients with severe, active rheumatoid arthritis who have had an inadequate response or intolerance to at least one tumour necrosis factor (TNF) inhibitor therapy.
Truxima has been shown to reduce the rate of progression of joint damage as measured by xray when given in combination with methotrexate.,Granulomatosis with polyangiitis (Wegener's) (GPA) and Microscopic polyangiitis (MPA)
Truxima in combination with glucocorticoids is indicated for the induction of remission in patients with severely active Granulomatosis with polyangiitis (GPA, also known as Wegener's granulomatosis) and Microscopic polyangiitis (MPA). The efficacy and safety of retreatment with rituximab have not been established.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Glass Type I Clear	48 Months	Store at 2 to 8 degrees Celsius	Neither child resistant closure nor restricted flow insert	Do not Freeze Protect from Light

Pack Size/Poison information

Pack Size	Poison Schedule
1	(S4) Prescription Only Medicine

Components

1 . TRUXIMA rituximab (rch) 500 mg/ 50 mL concentrate solution for intravenous infusion

Dosage Form	Injection, concentrated
Route of Administration	Intravenous Infusion
Visual Identification	Clear to opalescent, colourless to pale yellow liquid

Active Ingredients	
Rituximab	**500 mg**
Other Ingredients (Excipients)	
polysorbate 80	
sodium chloride	
sodium citrate dihydrate	
water for injections	

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