Medicines

Revised: 31 May 2019

Medsafe Product Detail

File ref: TT50-9444

Trade Name	*Dose Form*	*Strength*	*Identifier*
Inflectra	Powder for injection	100 mg	
Sponsor	*Application date*	*Registration situation*	*Classification*
Pfizer New Zealand Limited P O Box 3998 AUCKLAND 1140	27/11/2013	Not available Approval date: 17/9/2015 Notification date: 8/3/2016	Prescription

Reference product: Remicade, Powder for injection 100 mg (Prescription)

Composition

Component	*Ingredient*	*Manufacturer*
powder for injection	Active	
	Infliximab 100mg	Celltrion Inc. Plant II 20, Academy-ro 51 beon-gil Yeonsu-gu Incheon 22014 SOUTH KOREA Celltrion Inc. Plant I (CLT1) 23, Academy-ro Yeonsu-gu Incheon 22014 SOUTH KOREA
	Excipient	
	Dibasic sodium phosphate dihydrate	
	Monobasic sodium phosphate monohydrate	
	Polysorbate 80	
	Sucrose	

Production

Manufacturing step	*Manufacturer*
Finished Product Testing	Celltrion Inc. Plant I (CLT1) 23, Academy-ro Yeonsu-gu Incheon 22014 SOUTH KOREA Celltrion Inc. Plant II 20, Academy-ro 51 beon-gil Yeonsu-gu Incheon 22014 SOUTH KOREA
Manufacture of Final Dose Form	Celltrion Inc. Plant II 20, Academy-ro 51 beon-gil Yeonsu-gu Incheon 22014 SOUTH KOREA Gensenta Ilac Sanayii ve Ticaret A.S. Yenibosna Cobancesme Mahallesi Sanayi Caddesi No 13, Yenibosna-Bahcelievler Instanbul 34196 TURKEY
Secondary Packaging	Celltrion Inc. Plant II 20, Academy-ro 51 beon-gil Yeonsu-gu Incheon 22014 SOUTH KOREA DHL Supply Chain (New Zealand) Ltd 6 Manu Tapu Drive Mangere Auckland 2022 EGIS Pharmaceutical PLC Bokenyfoldi ut 118-120 Budapest 1165 HUNGARY
NZ Site of Product Release	Pfizer New Zealand Limited Level 10, 11 Britomart Place Auckland CBD Auckland 1010

Packaging

Package	*Contents*	*Shelf Life*
Vial, glass,	100 mg	48 months from date of manufacture stored at 2° to 8°C (Refrigerate, do not freeze) 24 hours reconstituted stored at or below 30°C 24 hours diluted stored at or below 30°C

Indications

Rheumatoid Arthritis
Inflectra is a ⬩Disease-Controlling Anti-Rheumatic Therapy" (DCART) indicated for:
· the reduction of signs and symptoms
· prevention of structural joint damage (erosions and joint space narrowing)
· improvement in physical function
in patients with active disease.
Inflectra should be given in combination with methotrexate.

Ankylosing Spondylitis
Inflectra is indicated for the reduction of signs and symptoms and improvement in physical function in patients with active disease.

Psoriatic Arthritis
Inflectra is indicated for:
· the reduction of signs and symptoms of arthritis
· improvement in physical function
· reduction in psoriasis as measured by PASI (a system which combines symptom evaluation and body surface area)
· prevention of worsening of disability
· inhibition of the progression of structural damage of active arthritis, as measured by x-ray in patients with active and progressive psoriatic arthritis.

Psoriasis
Inflectra is indicated for reducing signs and symptoms of Psoriasis and improving quality of life in patients with moderate to severe plaque psoriasis for whom phototherapy or conventional systemic treatments have been inadequate or are inappropriate.

Ulcerative Colitis
Inflectra is indicated for:
· reducing signs and symptoms
· inducing and maintaining clinical remission
· inducing mucosal healing
· improving quality of life
· reducing or discontinuing administration of corticosteroids
· reducing ulcerative colitis-related hospitalizations
· reducing the incidence of colectomy
in patients with active ulcerative colitis who have had an inadequate response to conventional therapy.

Crohn's disease
Adults (18 years and older)
Inflectra is indicated for:
· Treatment of moderate to severe Crohn's disease for the reduction of signs and symptoms, induction and maintenance of clinical remission, induction of mucosal healing, and improvement in quality of life in adult patients who have an inadequate response to conventional therapies. Inflectra enables patients to reduce or eliminate corticosteroid use
· Treatment of draining enterocutaneous fistulae in adult patients with fistulising Crohn's disease.

Inflectra is indicated for treatment of moderate to severe active Crohn's disease in children aged 6 to 17 years, who have not responded to a full and adequate course of conventional therapy, or who are intolerant to or have medical contraindications to such therapy. Efficacy and safety beyond 54 weeks are unknown.

Latest Regulatory Activity

Application Date	*Application Type*	*Change(s)*	*Status*	*Payment Date*	*Priority*
25/3/2024	Changed Medicine Notification	Data sheet - G2	Granted 13/5/2024	3/4/2024	
27/11/2013	New Higher-risk Medicine Application	Abridged new higher-risk medicine not containing a new active substance	Granted 17/9/2015	10/12/2013	