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Medicines

Revised: 31 May 2019

Medsafe Product Detail

File ref: TT50-11190

Trade Name	*Dose Form*	*Strength*	*Identifier*
IXIFI	Powder for injection	100 mg	
Sponsor	*Application date*	*Registration situation*	*Classification*
Pfizer New Zealand Limited P O Box 3998 AUCKLAND 1140	4/9/2023	Consent given Approval date: 21/8/2025	Prescription
	Reference product: Remicade, Powder for injection 100 mg (Prescription)		

Composition

Component	*Ingredient*	*Manufacturer*
powder for injection	Active	
	Infliximab 100mg	Boehringer Ingelheim Pharma GmbH & Co KG Birkendorfer Strasse 65 Biberach an der Riss 88397 GERMANY
	Excipient	
	Disodium succinate hexahydrate	
	Polysorbate 80	
	Succinic acid	
	Sucrose	

Production

Manufacturing step	*Manufacturer*
Finished Product Testing	Pfizer Ireland Pharmaceuticals Unlimited Company Grange Castle Business Park Nangor Road Dublin D22 V8F8 IRELAND
Finished Product Testing - Microbiological	Pfizer Manufacturing Belgium NV Rijksweg 12 Puurs-Sint-Amands B-2870 BELGIUM
Manufacture of Final Dose Form	Pfizer Manufacturing Belgium NV Rijksweg 12 Puurs-Sint-Amands B-2870 BELGIUM
Packing	Pfizer Manufacturing Belgium NV Rijksweg 12 Puurs-Sint-Amands B-2870 BELGIUM
Secondary Packaging	DHL Supply Chain (New Zealand) Ltd 6 Manu Tapu Drive Mangere Auckland 2022
	Pfizer Manufacturing Belgium NV Rijksweg 12 Puurs-Sint-Amands B-2870 BELGIUM
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, Type I, 15 mL, chlorobutyl stopper	100 mg	60 months from date of manufacture stored at 2° to 8°C (Refrigerate, do not freeze) 6 months from date of manufacture stored at or below 30°C. no return to refrigeration 18 hours reconstituted stored at or below 30°C 24 hours diluted stored at or below 30°C. following reconstitution

Indications

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

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

Psoriatic arthritis
IXIFI is indicated for:
- the reduction of signs and symptoms of arthritis
- improvement in physical function
- reduction in psoriasis as measured by PASI (an index 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. IXIFI should be administered:
- in combination with methotrexate, or
- alone in patients who show intolerance to methotrexate or for whom methotrexate is contraindicated.

Crohn's disease
Adults (NLT 18 years)
IXIFI is indicated for:
- treatment of moderate to severe Crohn's disease for the reduction of signs and symptoms, induction 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. IXIFI enables patients to reduce or eliminate corticosteroid use.
- treatment of draining enterocutaneous fistulae in adult patients with fistulising Crohn's disease.
Children and adolescents (6 to 17 Years)
IXIFI 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.

Psoriasis
IXIFI 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
In adults, and in children and adolescents (6 to 17 years),
IXIFI is indicated for the treatment of moderately severe to severe active ulcerative colitis in patients who have had an inadequate response to conventional therapy.

Latest Regulatory Activity

Application Date	*Application Type*	*Change(s)*	*Status*	*Payment Date*	*Priority*
4/9/2023	New Higher-risk Medicine Application	New higher-risk medicine that does not contain a new active substance	Granted 21/8/2025	20/9/2023	