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Medicines

Revised: 31 May 2019

Medsafe Product Detail

File ref: TT50-10961

Trade Name	*Dose Form*	*Strength*	*Identifier*
Renflexis	Powder for injection	100 mg	
Sponsor	*Application date*	*Registration situation*	*Classification*
Samsung Bioepis NZ Limited TMF Group Level 11, 41 Shortland Street Auckland 1010	1/10/2021	Not available Approval date: 16/3/2023 Notification date: 4/6/2025	Prescription

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

Composition

Component	*Ingredient*	*Manufacturer*
powder for injection	Active	
	Infliximab 100mg	FUJIFILM Diosynth Biotechnologies Denmark ApS Biotek Alle 1 Hillerod DK-3400 DENMARK
	Excipient	
	Dibasic sodium phosphate heptahydrate	
	Monobasic sodium phosphate monohydrate	
	Polysorbate 80	
	Sucrose	

Production

Manufacturing step	*Manufacturer*
Finished Product Testing	FUJIFILM Diosynth Biotechnologies Denmark ApS Biotek Alle 1 Hillerod DK-3400 DENMARK
Finished Product Testing - Microbiological	Charles River Laboratories Ireland Limited Carrentrila Ballina County Mayo IRELAND
	Patheon Italia S.p.A 2 Trav. SX, Via Morolense 5 Ferentino 03013 ITALY
Manufacture of Final Dose Form	Patheon Italia S.p.A 2 Trav. SX, Via Morolense 5 Ferentino 03013 ITALY
Packing	Patheon Italia S.p.A 2 Trav. SX, Via Morolense 5 Ferentino 03013 ITALY
Secondary Packaging	Farmaceutici Formenti S.p.A Via di Vittorio 2 Origgio 21040 ITALY
NZ Site of Product Release	Samsung Bioepis NZ Limited TMF Group Level 11, 41 Shortland Street Auckland 1010

Packaging

Package	*Contents*	*Shelf Life*
Vial, glass, Type I glass vial closed with bromobutyl rubber stopper and flip off cap	100 mg	48 months from date of manufacture stored at 2° to 8°C (Refrigerate, do not freeze)

Indications

Ulcerative Colitis in Adults and Children and Adolescents (6 to 17 years)
Renflexis is indicated for the treatment of moderately severe to severe active ulcerative colitis in patients who have had an inadequate response to conventional therapy.

Psoriasis
Renflexis 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.

Crohn's disease
Adults (18 years and older)
Renflexis 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. Renflexis 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)
Renflexis 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.

Psoriatic Arthritis
Renflexis 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.

Renflexis should be administered
- In combination with methotrexate, or
- Alone in patients who show intolerance to methotrexate or for whom methotrexate is contraindicated.

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

Rheumatoid Arthritis
Renflexis 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.

Renflexis should be given in combination with methotrexate.

Latest Regulatory Activity

Application Date	*Application Type*	*Change(s)*	*Status*	*Payment Date*	*Priority*
5/8/2025	Self-Assessable Change Notification	Data sheet - G1 (Self assessable)	Notified	15/8/2025	
1/10/2021	New Higher-risk Medicine Application	Abridged new higher-risk medicine not containing a new active substance	Granted 16/3/2023	6/12/2021	