

SUMMARY OF PRODUCT

STRUCTURE

Etanercept is a dimeric fusion protein consisting of the extracellular ligand-binding portion of the human 75 kDa (p75) tumor necrosis factor receptor (TNFR) linked to the Fc portion of human immunoglobulin (IgG1). This Fc component contains the hinge, CH2 and CH3 regions, but not the CH1 region of IgG1. Etanercept is produced by recombinant DNA technology in Chinese hamster ovary (CHO) mammalian cell expression system. It contains 934 amino acids and has an approximate molecular weight of 130 kDa.

Etanercept mainly is applied in treatment of autoimmune diseases such as Rheumatoid Arthritis, Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis and Juvenile Idiopathic arthritis.

Etanercept is supplied as a clear or almost clear, colorless to slightly yellow and preservative-free solution.

Amino Acid Sequence of Etanercept

LPAQVAFTPYAPEPGSTCRLREYYDQTAQMCCSKCSPGQHAKVFCTKTSDTVCDSCEDST	60
YTQLWNWVPECLSCGSRCSSDQVETQACTREQRICTRPGWYCALKQEGCRLCAPLRK	120
CRPGFGVARPGTETSDVVCKPCAPGTFSNNTSSTDICRPHQICNVVAIPGNASMDAVCTS	180
TSPTRSMAPGAVHLPQPVSTRSQHTQPTPEPSTAPSTSFLPMGSPPAEGSTGDEPKSC	240
DKTHTCPPCPAPELLGGPSVFLFPPKPKDTLMISRTPEVTCVVVDVSHEDPVKFNWYVD	300
GVQVHNAAKTKPREQQYNSTYRVVSVLTVLHQNWLDGKEYKCKVSNKALPAPIEKTIKAK	360
GQPREPQVYTLPPSREEMTKNQVSLTCLVKGFYPSDIAVEWESNGQPENNYKTPPVLDSDGSFFLYSKLTVDKSRWQQGNVFSCSVMHEALHNHYTQKSLSLSPGK	420
	467

Nomenclature information of Etanercept.

Recommended International Nonproprietary Name (INN)	Etanercept
Anatomical Therapeutic Chemical (ATC) code	L04AB01
Chemical Name	Human tumor necrosis factor receptor fusion protein
Chemical Abstracts Service (CAS) registry number	185243-69-0
Molecular Formula	<chem>C2224H3472N618O701S36</chem>
Molecular weight	~ 130 KDa

Name of the medicinal product

Altebrel 25 mg/0.5 mL solution for injection in prefilled syringe

Altebrel 50 mg/mL solution for injection in prefilled syringe

Reference Product

Enbrel from Pfizer

Quantitative and Qualitative composition

Each 0.5 mL single dose syringe contains 25 mg of Etanercept.

Etanercept is produced by recombinant DNA technology in a CHO mammalian cell.

Each syringe of Altebrel consist of Sodium chloride, Sucrose, L-Arginine Hydrochloride, Sodium phosphate monobasic dihydrate, Sodium phosphate dibasic dihydrate and water for injections.

Each 1.0 mL single dose syringe contains 50 mg of Etanercept.

Etanercept is produced by recombinant DNA technology in a CHO mammalian cell.

Each syringe of Altebrel consist of Sodium chloride, Sucrose, L-Arginine Hydrochloride, Sodium phosphate monobasic dihydrate, Sodium phosphate dibasic dihydrate and water for injections.

Therapeutic indications

Rheumatoid arthritis

Juvenile idiopathic arthritis

Axial spondyloarthritis

Psoriatic arthritis

Ankylosing spondylitis (AS)

Non-radiographic axial spondyloarthritis

Plaque psoriasis

Paediatric plaque psoriasis

Pharmacological properties

Pharmacotherapeutic group: Immunosuppressants, Tumour Necrosis Factor alpha (TNF- α) inhibitors, ATC code: L04AB01

Route of Administration

SC