

## 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

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LPAQVAFTPYAPEPGSTCRLREYYDQTAQMCCSKCSPGQHAKVFCTKTSDTVCDSCEDST 60
YTQLWNWVPECLSCGSRCSSDQVETQACTREQNRICRCRPGWYCALSKEGCRLCAPLRK 120
CRPGFGVARPGTETSDVVCCKPCAPGTFSTNTSSTDICRPHQICNVVAIPGNASMDAVCTS 180
TSPTRSMAPGAVHLPQPVSTRSQHTQPTPEPSTAPSTSFLLLPMGPSPPAEGSTGDEPKSC 240
DKTHTCPCPAPELLGGPSVFLFPPKPKDTLMISRTPEVTCVVVDVSHEDPQVKFNWYVD 300
GVQVHNAKTKPREQQYNSTYRVVSVLTVLHQNWLDGKEYKCKVSNKALPAPIEKTISKAK 360
GQPREPQVYTLPPSREEMTKNQVSLTCLVKGFYPSDIAVEWESNGQPENNYKTTPVLDS 420
DGSFFLYSKLTVDKSRWQQGNVFCSSVMHEALHNHYTQKSLSLSPGK 467
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## Nomenclature information of Etanercept.

<b>Recommended International Nonproprietary Name (INN)</b>	Etanercept
<b>Anatomical Therapeutic Chemical (ATC) code</b>	L04AB01
<b>Chemical Name</b>	Human tumor necrosis factor receptor fusion protein
<b>Chemical Abstracts Service (CAS) registry number</b>	185243-69-0
<b>Molecular Formula</b>	C <sub>2224</sub> H <sub>3472</sub> N <sub>618</sub> O <sub>701</sub> S <sub>36</sub>
<b>Molecular weight</b>	~ 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- $\alpha$ ) inhibitors, ATC code: L04AB01

**Route of Administration**

SC