

Summary of Enbrel (etanercept) Safety Information - Argentina

Enbrel is a fusion protein produced using recombinant DNA technology that inhibits tumor necrosis factor alpha (TNF- α). ATC Code: L04AB01.

Pharmaceutical form: Solution for subcutaneous injection.

INDICATIONS: Rheumatoid arthritis, juvenile idiopathic arthritis (JIA) from 2 years of age, enthesitis-related arthritis in adolescents from 12 years of age, psoriatic arthritis, ankylosing spondylitis (axial spondyloarthritis), non-radiographic axial spondyloarthritis, plaque psoriasis in adults and children aged 6 years and older.

CONTRAINDICATIONS: Hypersensitivity to etanercept or any of the components of the formulation, sepsis or risk of sepsis. Enbrel (etanercept) should not be administered to patients with serious, chronic, or localized active infections.

WARNINGS / PRECAUTIONS: Allergic reactions have been reported. It may affect the host's defenses against infections and neoplasms.

MOST COMMON ADVERSE REACTIONS: Infections, headache, allergic reactions, injection site reactions (erythema, itching, pain, and swelling).

INCOMPATIBILITIES: Do not mix with other medications.

STORAGE: Refrigerate between 2°C and 8°C. Do not freeze. Keep syringes, autoinjectors, or cartridges in the box to protect them from light.

PREGNANCY: Etanercept crosses the placenta and has been detected in the serum of infants born to women treated with etanercept during pregnancy. The clinical significance of this finding is unknown; however, infants may have an increased risk of infection.

BREASTFEEDING: The use of etanercept during breastfeeding may be considered, taking into account the benefit of breastfeeding for the infant and the benefit of treatment for the mother.”