

Human CD3 x CD19 (Blinatumomab) Antibody

Biosimilar Recombinant Human Monoclonal Antibody

Product Information

Product No.: C2530

Clone: AMG103

Isotype: Human IgG1κ

Storage: Sterile 2° to 8°C

Product Description

Specificity:

This non-therapeutic biosimilar antibody uses the same variable region sequence as the therapeutic antibody Blinatumomab. Blinatumomab simultaneously binds human CD19 on B cells and CD3E on T cells.

Antigen Distribution:

CD19 is a surface antigen present on all B cells (healthy and malignant) except hematopoietic stem cells and plasma cells; it is highly conserved in B-cell malignancies. CD3E is a T cell surface glycoprotein.

Background:

Blinatumomab is a Bispecific T cell Engager (BiTE) antibody developed as a cancer immunotherapeutic drug^{1,2,3,4}. Blinatumomab induces apoptosis of target B cells by binding simultaneously to the CD19 surface antigen of all B cells (healthy and malignant) as well as the epsilon subunit of the CD3 invariant antigen of the T cell TCR (T cell receptor)⁴. Binding is achieved via two large single-chain variable fragments arranged in tandem, with the CD19-binding fragment at the N-terminal and the CD3 binding fragment at the C-terminal. The fragments are linked by a flexible, non-immunogenic, non-glycosylated five amino acid peptide (four glycine and one serine), which confers a high degree of rotational flexibility to facilitate simultaneous epitope binding. In this way, blinatumomab targets malignant B cells for apoptosis via CD19, a B-lymphocyte-specific receptor responsible for promoting activation and differentiation of normal B cells that functions as a costimulatory molecule of the B cell receptor².

Blinatumomab binding forces the colocalization of cytotoxic T lymphocytes and B cells expressing CD19⁴. A structurally normal cytolytic immune synapse is formed, and, in T cells, activation events trigger the delivery of granzyme and perforin into the synaptic space, inducing apoptosis of the targeted B cells. Recruitment and activation of T cells occurs after the second arm of blinatumomab binds to the target cell antigen. An activated T cell can kill several B cells.

Blinatumomab is a B lineage-specific antitumor mouse monoclonal antibody⁴. The CD19-targeting fragment is derived from the parental murine monoclonal antibody HD37, while the CD3-binding fragment is derived from the parental murine monoclonal antibody L2K-071^{3,4}. Blinatumomab is only one-third the size of traditional antibodies at 504 amino acids and a molecular weight of 55 kDa⁴. Other names for blinatumomab are MT103, MEDI-538, bscCD19xCD3, and AMG103. Blinatumomab is a non-glycosylated fusion protein.

Known Reactivity Species:

Human

Expression Host:

HEK-293 Cells

Format:

Purified No Carrier Protein

Immunogen:

CD19 murine parental clone is HD37. CD3E murine parental clone is L2K-07.

Formulation

This biosimilar antibody is aseptically packaged and formulated in 0.01 M phosphate buffered saline (150 mM NaCl) PBS pH 7.2 - 7.4 with no carrier protein, potassium, calcium or preservatives added. Due to inherent biochemical properties of antibodies, certain products may be prone to precipitation over time. Precipitation may be removed by aseptic centrifugation and/or filtration.

Purity

≥95% by SDS Page, ≥95% monomer by analytical SEC

Endotoxin

≤ 1.0 EU/mg as determined by the LAL method

Storage and Stability

Functional grade biosimilar antibodies may be stored sterile as received at 2-8°C for up to one month. For longer term storage, aseptically aliquot in working volumes without diluting and store at -80°C.

Avoid Repeated Freeze Thaw Cycles.

Product Preparation

Recombinant biosimilar antibodies are manufactured in an animal free facility using only in vitro protein free cell culture techniques and are purified by a multi-step process including the use of protein A or G to assure extremely low levels of endotoxins, leachable protein A or aggregates.

Pathogen Testing

To protect mouse colonies from infection by pathogens and to assure that experimental preclinical data is not affected by such pathogens, all of Leinco's recombinant biosimilar antibodies are tested and guaranteed to be negative for all pathogens in the IDEXX IMPACT I Mouse Profile.

Other Applications Reported in Literature:

FA,
FC,
IP,
WB

Country of Origin

USA

References

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- 5) Dreier T, Lorenczewski G, Brandl C, et al. Int J Cancer. 100(6):690-697. 2002.
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