

Anti-Human GD2 (Dinutuximab) Fc Muted™

Biosimilar Recombinant Human Monoclonal Antibody

Product Information

Product No.: G165

Clone: APN311

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 Dinutuximab. This product is for research use only. Dinutuximab activity is directed against human disialoganglioside (GD2).

Antigen Distribution:

GD2 is a cell surface glycolipid present in low concentrations on skin, neural or peripheral nerve cell surfaces. GD2 is overexpressed on neuroblastoma cells, most melanoma, and some other tumors

Background:

Neuroblastoma is an extracranial childhood cancer that accounts for 12% of cancer deaths in children¹. Neuroblastomas highly express the antigen GD2, a glycolipid which assists in the attachment of tumor cells to the extracellular matrix².

Dinutuximab is a mouse-human chimeric monoclonal antibody to disialoganglioside (GD2)³. Engagement of dinutuximab with GD2 triggers antibody dependent cell cytotoxicity and complement dependent cytotoxicity, the effectiveness of which is increased by coadministration with granulocyte-macrophage colony stimulating factor (GM-CSF), interleukin-2 (IL-12), and 13-cis retinoic acid (isotretinoin).

Dinutuximab, also known as ch14.18, was developed as an IgG1 human/mouse chimeric switch variant of murine monoclonal antibody 14.18⁴. Dinutuximab is composed of the variable heavy- and light-chain regions of the murine anti-GD2 mAb 14.18 and the constant regions of human IgG1 heavy-chain and κ light-chain. Dinutuximab is produced in the murine myeloma cell line SP2/O and has an approximate molecular weight of 150 kDa⁵. Studies have also tested the efficacy of dinutuximab grown in Chinese hamster ovary (CHO) cells (ch14.18/CHO)^{6,7}.

Known Reactivity Species:

Human

Expression Host:

HEK-293 Cells

Format:

Purified No Carrier Protein

Immunogen:

Humanized antibody derived from mouse clone ch14.18

Products are for research use only. Not for use in diagnostic or therapeutic procedures.

410 Axminster Dr, St. Louis, MO 63026

(800) 538-1145

leincoglobal@leinco.com

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 preclinical antibodies may be stored sterile as received at 2 to 8°C for up to one month. For longer term storage, aseptically aliquot in working volumes without diluting and store at ≤ -70°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.

Other Applications Reported in Literature:

**ELISA,
FA,
FC**

Country of Origin

USA

References

- 1) Aust Prescr. 43(6):212-213. 2020.
- 2) Hoy SM. Target Oncol. 11(2):247-253. 2016.
- 3) Dhillon S. Drugs. 75(8):923-927. 2015.
- 4) Mueller BM, Romerdahl CA, Gillies SD, et al. J Immunol. 144(4):1382-1386. 1990.
- 5) [https:// www.unituxin.com/full-prescribing-information.pdf](https://www.unituxin.com/full-prescribing-information.pdf)
- 6) Ladenstein R, Weixler S, Baykan B, et al. MAbs. 5(5):801-809. 2013.
- 7) Ladenstein R, Pötschger U, Valteau-Couanet D, et al. Lancet Oncol. 19(12):1617-1629. 2018.
- 8) Barker E, Mueller BM, Handgretinger R, et al. Cancer Res. 51(1):144-149. 1991.
- 9) Yu AL, Gilman AL, Ozkaynak MF, et al. N Engl J Med. 363(14):1324-1334. 2010.