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RSV F Protein (Nirsevimab) Antibody

Biosimilar Recombinant Human Monoclonal Antibody

Product Information

Product No.:	R210
Clone:	MEDI8897
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 Nirsevimab. Nirsevimab binds the F1 and F2 subunits of the prefusion RSV F protein at a highly conserved epitope in antigenic site Ø.

Antigen Distribution:
F protein is found in RSV virion membranes in either an inactive prefusion conformation or an active postfusion conformation.

Background:
Respiratory syncytial virus (RSV) is a major cause of acute lower respiratory tract infection and hospitalization in infants1. RSV F protein is a type I integral membrane protein essential for viral membrane fusion that is highly conserved among isolates of RSV A and B subgroups2. F protein has been investigated as a target for neutralizing antibodies, small molecular antiviral drug development, as a vaccine antigen, and as an antibody target for passive prophylaxis.

F protein is synthesized as an inactive, palmitoylated precursor (F0) and is decorated with N-linked glycans2. Three F0 monomers form a trimer and become activated by a furin-like host protease as they pass through the Golgi. The protease cleaves twice, generating three polypeptides: F2 and F1, which are covalently linked, and pep27, an intervening peptide that dissociates after cleavage. When functional F protein trimer in the virion membrane is triggered, it undergoes a major conformational change from a prefusion to postfusion form. Approximately 25% of isolate specific variability for F protein is found within an antigenic site at the apex of the prefusion trimer (antigenic site Ø), composed of an α-helix from F1 (aa 196–210) and a strand from F2 (aa 62–69).

Nirsevimab is a long-acting, neutralizing recombinant human monoclonal antibody that binds the F1 and F2 subunits of F protein at a highly conserved epitope in antigenic site Ø and locks the RSV F protein in the prefusion conformation, blocking viral entry into the host cell1, 3, 4. In vitro, nirsevimab binds to immobilized human FcγRs (FcγRI, FcγRIIA, FcγRIIB and FcγRIII)3. Protection from infection is thought to be dependent on neutralization activity rather than Fc-mediated effector function based on data from a cotton rat model of RSV infection3. Nirsevimab has been modified with a triple amino acid substitution (YTE) in the Fc region to extend the serum half-life3. Nirsevimab originates from the D25 antibody developed by AIMM Therapeutics and was jointly developed and commercialized by AstraZeneca and Sanofi for the prevention of RSV infection in neonates and infants.

Known Reactivity Species:
Human

Expression Host:
HEK-293 Cells

Format:
Purified No Carrier Protein

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Immunogen:
Prefusion RSV F protein

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:
FA,
ELISA

Country of Origin
USA

References
1) Hammitt LL, Dagan R, Yuan Y, et al. N Engl J Med. 386(9):837-846. 2022.
2) McLellan JS, Ray WC, Peeples ME. Curr Top Microbiol Immunol. 372:383-104. 2013.
3) Keam SJ. Drugs. 83(2):181-187. 2023.
4) Zhu Q, McLellan JS, Kallewaard NL, et al. Sci Transl Med. 9(388):eaaj1928. 2017.
5) Domachowske JB, Khan AA, Esser MT, et al. Pediatr Infect Dis J. 37(9):886-892. 2018.
6) Zhu Q, Lu B, McTamney P, et al. J Infect Dis. 218(4):572-580. 2018.
7) Griffin MP, Yuan Y, Takas T, et al. N Engl J Med. 383(5):415-425. 2020.