



18 September 2025
EMA/CHMP/274513/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Enflonsia clesrovimab

On 18 September 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Enflonsia, intended for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants during their first RSV season. The applicant for this medicinal product is Merck Sharp & Dohme B.V.

Enflonsia will be available as a 105 mg solution for injection in pre-filled syringes. The active substance of Enflonsia is clesrovimab, an antiviral monoclonal antibody (ATC code: J06BD10). Clesrovimab is a fully human immunoglobulin G1 kappa (IgG1 κ) neutralising monoclonal antibody with a triple amino acid substitution in the Fc region which increases binding to the neonatal Fc receptor leading to an extended serum half-life. Clesrovimab provides passive immunity by targeting the RSV outer membrane fusion protein to prevent viral entry into cells.

The benefit of Enflonsia is the prevention of RSV lower respiratory tract disease in neonates and infants during their first RSV season. The most common side effects include injection-site pain, injection-site erythema, injection-site swelling and rash.

The full indication is:

Enflonsia is indicated for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants during their first RSV season.

Enflonsia should be used in accordance with official recommendations.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

