



# Help Surround Your Infants With RSV Protection

The first and only long-acting RSV mAb with  
**one dose** for infants, regardless of weight<sup>1-3</sup>



One dose  
regardless  
of weight<sup>1</sup>



Protection across  
the full length of a  
typical RSV season  
(October - February)<sup>1,4</sup>



The only RSV mAb to  
target antigenic site  
IV on the RSV fusion  
(F) protein<sup>1,5</sup>

ENFLONISIA® is indicated for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants during their first RSV season.<sup>1</sup>



## Eligibility

# Protect the infants in your care with ENFLONZIA®

JCVI advised that mAbs for at-risk infant groups should continue during the RSV season, alongside a universal programme of maternal vaccination.<sup>4</sup>

The UKHSA Green Book recommends ENFLONZIA® as an option for use in:



Very and extremely **preterm** infants (born before 32 weeks gestation) through selective immunisation<sup>4</sup>



Infants and young children at **high risk** of severe RSV disease through selective immunisation, including infants with<sup>4</sup>:

- Congenital heart disease (CHD)
- Chronic lung disease of prematurity (CLD), also known as bronchopulmonary dysplasia (BPD)
- Severe Combined Immunodeficiency Syndrome (SCID)

Please consult Chapter 27a of the UKHSA Green Book (June 2026) for full eligibility criteria for high-risk infants.

## Be ready this RSV season

### Scan or click to unlock practical resources

Stay ahead this RSV season. Scan or click below to unlock practical resources, patient materials, and updates from MSD – built to help you support infants and their parents with confidence.

**I would like to receive resources**

### Scan or click to consent

By scanning or clicking and submitting your details, you are providing your consent for MSD to contact you with communications relevant to your practice, some of which may be promotional in nature. You can withdraw your consent at any time by contacting your MSD representative or via the unsubscribe link provided in any communication. For more information on how MSD processes your personal data, please see our Privacy Notice.



# CLEVER (Efficacy)

## Designed to evaluate the efficacy & safety of ENFLONSIA® (vs placebo) during the first RSV season<sup>1</sup>

**Study design:** Phase 2b/3, randomised, double-blind, placebo-controlled study of healthy infants who are early or moderately pre-term ( $\geq 29$  weeks to 34 weeks and 6 days GA) and late preterm or full-term infant ( $\geq 35$  weeks GA). Infants were randomised 2:1 to receive 105 mg IM of ENFLONSIA® (N=2,412) or placebo (N=1,202).<sup>6</sup>

**Primary endpoint:** The incidence of RSV-associated medically attended LRI requiring  $\geq 1$  hospitalisation through 150 days after dosing.<sup>6</sup>

**Secondary endpoint:** Efficacy of ENFLONSIA® against RSV-associated hospitalisation, Days 1-150 (hypothesis testing).<sup>6</sup>

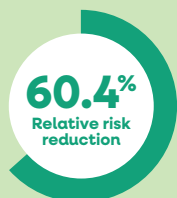
### INCIDENCE OF RSV-ASSOCIATED DISEASE IN PRETERM AND FULL-TERM INFANTS DAYS 1 THROUGH 150 POST-DOSE

#### Primary Endpoint

##### Medically Attended LRI<sup>a</sup>

(95% CI: 44.1, 71.9;  $p < 0.001$ )

3.9% difference in incidence rate

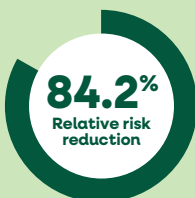


#### Secondary Endpoint

##### Hospitalisation<sup>b</sup>

(95% CI: 66.6, 92.6;  $p < 0.001$ )

2% difference in incidence rate

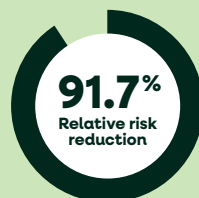


#### Exploratory Endpoint\*

##### Severe Medically Attended LRI

(95% CI: 62.9, 98.1)

0.9% difference in incidence rate



INCREASING EFFICACY WITH INCREASING DISEASE SEVERITY →

#### Cough or difficulty breathing



$\geq 1$  indicator of LRI

(Wheezing, rales/crackles)

or

$\geq 1$  indicator of severity

(Chest wall in-drawing/retractions, hypoxemia, tachypnea, and dehydration due to respiratory symptoms)

#### Admitted for respiratory illness

#### Cough or difficulty breathing



Severe disease

(Severe hypoxemia or the need for supplemental oxygen or mechanical ventilatory support)

\*Exploratory efficacy endpoint, not multiplicity controlled.

All efficacy endpoints evaluated required an RSV-positive RT-PCR NP sample.<sup>1</sup>

<sup>a</sup>The statistical criterion for success required the lower bound of the 95% CI of efficacy to be  $>25\%$ .<sup>1</sup>

<sup>b</sup>The statistical criterion for success required the lower bound of the 95% CI of efficacy to be  $>0\%$ .<sup>1</sup>



**ENFLONSIA® provides direct, rapid protection across the broadest spectrum of RSV disease, from mild to severe disease, in healthy and high-risk babies.<sup>1</sup>**

# CLEVER (Safety)



**Medically attended events:** In the CLEVER trial, the definition of medically attended events was aligned to WHO definitions.<sup>7</sup> As this included routine, outpatient, and hospital settings, the definition reflected the full spectrum of RSV observed in clinical practice.<sup>1,8</sup>

CLEVER: Summarised table of adverse events<sup>6,\*</sup>

| Adverse Events                                                  | ENFLONSIA®<br>(N=2,409)     | Placebo<br>(N=1,202) | Estimated<br>difference (95% CI) |
|-----------------------------------------------------------------|-----------------------------|----------------------|----------------------------------|
|                                                                 | Number of infants (percent) |                      | Percentage points                |
| Drug-related adverse events                                     | 696 (28.9)                  | 344 (28.6)           | 0.3 (-2.9 to 3.4)                |
| Drug-related serious adverse events                             | 1 (<0.1)                    | 1 (0.1)              | 0.0 (-0.4 to 0.2)                |
| Summarised solicited adverse events on days 1-5 after injection |                             |                      |                                  |
| Injection-site erythema                                         | 107 (4.4)                   | 43 (3.6)             | 0.9 (-0.6 to 2.2)                |
| Injection-site pain                                             | 156 (6.5)                   | 96 (8.0)             | -1.5 (-3.4 to 0.2)               |
| Injection-site swelling                                         | 77 (3.2)                    | 38 (3.2)             | 0.0 (-1.3 to 1.2)                |
| Adverse events of special interest                              |                             |                      |                                  |
| Anaphylaxis or hypersensitivity                                 | 1 (<0.1)                    | 0                    | 0.0 (-0.3 to 0.2)                |
| Rash                                                            | 11 (0.5)                    | 4 (0.3)              | 0.1 (-0.4 to 0.5)                |

\*Adapted from Zar et. al, 2025

Adverse events were specifically solicited, ensuring a comprehensive reporting of mild-to-moderate adverse events, reflective of real-world experience.<sup>1</sup>



**ENFLONSIA® demonstrates a consistent safety profile in healthy infants vs placebo. Most (>96%) of the adverse reactions were mild to moderate.<sup>1</sup>**



This is a photo of a fictional infant and is for illustrative purposes only.

GA, gestational age; IM, intramuscular; LRI, lower respiratory infection; MALRI, medically attended lower respiratory infection; RSV, respiratory syncytial virus.

Designed to evaluate the safety of ENFLONSIA® vs palivizumab in high-risk and preterm infants<sup>1,9</sup>

ENFLONSIA® is indicated for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants during their first RSV season.<sup>1</sup>

**Study design:** Phase 3, randomised, partially masked, active comparator-controlled trial of infants at increased risk of severe RSV disease. This included infants who were ≤1 year of age and entering their first RSV season were preterm (≤35 weeks gestational age), had CLD of prematurity or haemodynamically significant CHD of any gestational age. Participants received a single 105 mg IM dose of ENFLONSIA® (n=498) followed by a dose of placebo one month later or 3 to 5 monthly doses of 15 mg/kg palivizumab (n=499).<sup>9</sup>

**Primary endpoint:** Proportions of participants with AEs, including solicited (injection site and systemic) AEs, or drug-related AEs, and SAEs.<sup>9</sup>

SMART: Summarised table of adverse events<sup>3,\*</sup>

| Adverse Events                      | ENFLONSIA®<br>(N=497)       | Palivizumab<br>(N=499) | Estimated difference<br>vs palivizumab (95% CI) |
|-------------------------------------|-----------------------------|------------------------|-------------------------------------------------|
|                                     | Number of infants (percent) |                        | Percentage points                               |
| Drug-related adverse events         | 152 (30.6)                  | 178 (35.7)             | -5.1 (-10.9 to 0.8)                             |
| Drug-related serious adverse events | 0 (0.0)                     | 2 (0.4)                | -0.4 (-1.5 to 0.4)                              |
| Summarised solicited adverse events |                             |                        |                                                 |
| Injection-site erythema             | 31 (6.2)                    | 32 (6.4)               | -0.2 (-3.3 to 2.9)                              |
| Injection-site pain                 | 39 (7.8)                    | 54 (10.8)              | -3.0 (-6.7 to 0.7)                              |
| Injection-site swelling             | 31 (6.2)                    | 28 (5.6)               | 0.6 (-2.4 to 3.6)                               |
| Adverse events of special interest  |                             |                        |                                                 |
| Anaphylaxis or hypersensitivity     | 0 (0.0)                     | 0 (0.0)                | 0.0 (-0.8 to 0.8)                               |
| Rash                                | 3 (0.6)                     | 1 (0.2)                | 0.4 (-0.6 to 1.6)                               |

\*Adapted from Zar et. al, 2026



ENFLONSIA® demonstrates a similar safety profile in infants at increased risk of severe RSV vs palivizumab.<sup>6</sup>

AE, adverse event; CHD, congenital heart disease; CI, confidence interval; CLD, chronic lung disease; IM, intramuscular; RSV, respiratory syncytial virus; SAE, serious adverse event.

# 1 Dose Regardless of Weight<sup>1</sup>

One dose is proven to be efficacious against RSV across all body weight, gestational age, and chronological age subgroups in CLEVER, covering the whole eligible trial cohort.<sup>6</sup>

## Simplify Your Immunisation Pathway from Delivery to Dose

### 1. Simplify Ordering and Inventory Management

One dose and compact packaging (~25% smaller than other long-acting mAbs).<sup>110</sup>

- ✓ Save a quarter of your fridge space

### 3. Execute RSV Prevention Programmes

One standardised dose may reduce operational complexity when implementing new RSV programmes.<sup>1</sup>

- ✓ Supporting multidisciplinary teams to deliver protection efficiently



### 2. Alleviate Administration Burden

No weight verification or weight based dose selection needed — same 105 mg dose administered as a single 0.7 mL intramuscular (IM) injection for every eligible infant.<sup>1</sup>

- ✓ Less time spent on training, weight checks and dose calculation — and more time for patient care

# 1 Additional Option For Reliable Supply

Our wholesale partner Alliance Healthcare is stocked with ENFLONISIA® across all branches and is ready to fulfil orders.

Hospitals with indicative volume requirements can contact Alliance Healthcare directly at [customerservice@alliance-healthcare.co.uk](mailto:customerservice@alliance-healthcare.co.uk), providing their account details and required units to help support stock planning.



MSD ensures robust manufacturing planning and multiple mitigation measures are in place to support the reliable supply of ENFLONISIA® throughout the RSV season.

#### References:

1. ENFLONSIA®. Summary of Product Characteristics. MSD; 2026
2. Beyfortus. Summary of Product Characteristics. Sanofi; 2025.
3. Synagis. Summary of Product Characteristics. AstraZeneca; 2023
4. UK Health Security Agency. The Green Book Chapter 27a Respiratory Syncytial Virus. June 2026. Accessed June 2026. Available at: [https://assets.publishing.service.gov.uk/media/6a2015a4730aece621f09866/Green\\_Book\\_RSV\\_20260603.pdf](https://assets.publishing.service.gov.uk/media/6a2015a4730aece621f09866/Green_Book_RSV_20260603.pdf).
5. Tang A, Chen Z, Cox KS, et al. A potent broadly neutralizing human RSV antibody targets conserved site IV of the fusion glycoprotein. *Nat Commun.* 2019;10(1):4153. <https://www.ncbi.nlm.nih.gov/pubmed/31515478>.
6. Zar HJ, Simões EAF, Madhi SA, et al. Clesrovimab for Prevention of RSV Disease in Healthy Infants. *N Engl J Med.* 2025;393(13):12921303. <https://pubmed.ncbi.nlm.nih.gov/40961446/>.
7. Modjarrad K, Giersing B, Kaslow DC, Smith PG, Moorthy VS. WHO consultation on Respiratory Syncytial Virus Vaccine Development: Report from a World Health Organization Meeting held on 23–24 March 2015. *Vaccine.* 2016;34(2):190–197. <https://www.sciencedirect.com/science/article/pii/S0264410X15007677>.
8. Englund JA, Cohen RA, Bianco V, Domachowske JB, Langley JM, Madhi SA, et al. Evaluation of Clinical Case Definitions for Respiratory Syncytial Virus Lower Respiratory Tract Infection in Young Children. *Journal of the Pediatric Infectious Diseases Society [Internet].* 2023 May 31 [cited 2026 July 8];12(5):273–81. Available from: <https://academic.oup.com/jpids/article/12/5/273/7152632?login=true>.
9. Zar HJ, Bont LJ, Manzoni P, et al. Clesrovimab in Infants at Increased Risk For Severe Disease During 2 RSV Seasons: A Randomized Clinical Trial. *JAMA Pediatr.* Published online July 20, 2026. doi:10.1001/jamapediatrics.2026.2760.
10. ENFLONSIA® & Beyfortus Pack Sizes. Data on File. MSD; 2026

**Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Merck Sharp & Dohme (UK) Limited (Tel: 0208 154 8000)**

#### Prescribing information is available [here](#)

Consult the Summary of Product Characteristics for further before prescribing, particularly in relation to side effects, precautions and contraindications.



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