Prescribing Information for ENFLONSIA®▼ (Clesrovimab) and adverse event reporting can be found here.

ENFLONSIA®▼ (clesrovimab) 105 mg injection

Information Pack

Purpose of this document

This document is to support healthcare professionals in the completion of a formulary application for ENFLONSIA® (Clesrovimab) for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants during their first RSV season. (MSD (UK) Ltd, 2026) This material may also be used to inform the development of clinical guidelines for the use of Clesrovimab within its licensed indication.

This document is intended for digital viewing only. Please do not print.

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). By clicking the above link, you will be taken to the MHRA website (a third-party website).

MSD does not recommend the use of any of its products outside any terms of its marketing authorisation indications. Always refer to the Summary of Product Characteristics before prescribing to help minimise the risks associated with the use of ENFLONSIA® (Clesrovimab).

This information pack has been produced by Merck Sharp & Dohme (UK) Limited.

You must check that all information included in the formulary pack is up to date, relevant, and consistent with the expected format of the local formulary application. MSD takes no responsibility for how this information is used by authors of documents referencing this document.

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Referencing

Referencing within this pack is in a modified Harvard style, e.g. (Author A, 2023). This is to ensure that references remain clear and consistent. Please ensure that you include all relevant full citations when utilising information from this information pack.

Abbreviations

Abbreviations have been avoided wherever possible, so that sections of this document can be used in isolation without confusion.

To provide your consent to receive further resources, some of which may be promotional in nature, click here or scan the QR code which will take you to MSD's promotional website for healthcare professionals.

Part 1: Medicinal product details and proposed place in therapy

Non-proprietary name: Clesrovimab (MSD (UK) Ltd, 2026)

Brand name: ENFLONSIA®▼ (MSD (UK) Ltd, 2026)

Dosage form: Solution in a pre-filled syringe for injection (MSD (UK) Ltd, 2026)

Manufacturer: Merck Sharp & Dohme (UK) Ltd (MSD (UK) Ltd, 2026)

Licensed indication: The prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants (children less than 12 months of age) during their first RSV season. (MSD (UK) Ltd, 2026)

Place in therapy recommended by National/Professional guidance

The guidance provided below up until and including Table 1 is adapted from Chapter 27a of the Green Book (June 2026) (UKHSA, 2026)

To reduce the risk of severe disease, infants born very or extremely prematurely (<32 weeks gestational age) are recommended to receive a dose of a long-acting monoclonal antibody, clesrovimab or nirsevimab (Sanofi, 2026), during or preceding their first RSV season.

To reduce the risk of severe disease, eligible high-risk infants are recommended to receive RSV monoclonal antibody immunisation seasonally. This should be offered regardless of whether the mother was vaccinated during the pregnancy.

Clesrovimab or nirsevimab (Sanofi, 2026) are the recommended first-line immunisations, if available. Palivizumab (AstraZeneca UK Limited, 2026) is recommended if neither of the first line products are available.

See Box 1 for further details of the conditions that classify an infant as high risk. (UKHSA, 2026)

Typically infants being discharged from hospital for the first time between mid September and the end of February should be immunised with clesrovimab or nirsevimab (Sanofi, 2026) while an inpatient. Those leaving hospital of the first time from the start of March to first half of September should be invited for outpatient immunisation scheduled in the second half of September or first half of October. Health service operational guidance should be followed.

Box 1. High Risk due to chronic lung disease (CLD) of prematurity, also known as bronchopulmonary dysplasia (BPD).

Moderate or severe CLD is defined as ‘pre-term infants with compatible x-ray changes who continue to receive supplemental oxygen or respiratory support at 36 weeks post-menstrual age’. Infants who fall into the light and dark red shaded area of Table 1 should be offered prophylaxis.

Infants with respiratory diseases who are not necessarily pre-term, but who remain in oxygen at the start of the RSV season are also considered to be a higher risk.

These infants may include those with conditions including:

- Pulmonary hypoplasia due to congenital diaphragmatic hernia
- Other congenital lung abnormalities (sometimes also involving congenital heart disease or lung malformation)
- Interstitial lung disease
- Those receiving long-term ventilation (LTV) at the onset of the first season

High risk due to congenital heart disease (CHD)

Preterm infants with haemodynamically significant, acyanotic CHD at the chronological ages at the start of the RSV season and gestational ages at birth covered within the light red shaded area in Table 1. Infants with cyanotic or acyanotic CHD plus significant co-morbidities particularly if multiple organ systems are involved.

High risk due to Severe Combined Immunodeficiency Syndrome (SCID)

Infants with SCID – the most severe form of inherited deficiency of immunity, who are unable to mount either T-cell responses or produce antibody against infectious agents.
(UKHSA, 2026)

Table 1 – Recommended use of monoclonal antibodies in at risk patients by gestational age

	Gestational age at birth (weeks+days)						
Chronological age (months)	24+0	24+1 to 26+0	26+1 to 28+0	28+1 to 30+0	30+1 to 32+0	32+1 to 34+0	≥34+1
<1.5							
1.5 to <3							
3 to <6							
6 to <9							
9							

Light red shaded area denotes eligibility for premature infants with haemodynamically significant acynanotic congenital heart disease; light or dark red areas denote eligibility for preterm infants with chronic lung disease. Note that most infants under consideration for eligiblity in this table are also eligible through the very and extremely preterm criteria.
(UKHSA, 2026)

Proposed formulary indication

The prevention of RSV lower respiratory tract disease in pre-term infants (≤32 weeks' gestational age) and infants at high risk of severe RSV disease as outlined by the green book, entering their first RSV season. (UKHSA, 2026)

Prescribing restrictions proposed

- Restricted to hospital prescribing
- Restricted to specialty/team

Proposed RAG rating (NOTE: Adjust wording according to local needs)

Red

Drugs considered to be specialist medicines and prescribing responsibility for these medicines should normally remain with the consultant or specialist clinician. These drugs should not be initiated or prescribed in primary care. It is recommended that the supply of these specialist medicines should be organised via the hospital pharmacy or specialist service.

Dosing: Neonates and infants: first RSV season

The recommended dose is 105 mg administered as a single 0.7 mL intramuscular (IM) injection.

For neonates and infants born during the RSV season, ENFLONSIA should be administered starting from birth. For infants born outside the RSV season, it should be administered once prior to the start of their first RSV season.

Dosing in infants with a body weight between 0.5 kg and 1.1 kg is based on extrapolation; no clinical data are available. Exposure in infants < 1.1 kg is anticipated to yield higher exposures than in those weighing more. The benefits and risks of clesrovimab in infants < 1.1 kg should be carefully considered.

There are limited clinical data available in extremely preterm infants (gestational age (GA) < 29 weeks) who are of chronological age less than 8 weeks. No clinical data are available in infants with a postmenstrual age (GA plus chronological age) of less than 32 weeks.

Infants undergoing cardiac surgery with cardiopulmonary bypass

For infants undergoing cardiac surgery with cardiopulmonary bypass during the RSV season, an additional 105 mg dose is recommended as soon as the infant is stable after surgery to ensure adequate clesrovimab serum levels.

Method of administration

ENFLONSIA is for intramuscular use only.

The medicinal product should be administered intramuscularly by a healthcare professional, in the anterolateral aspect of the thigh. It should not be injected in the gluteal area or areas where there may be a major nerve trunk and/or blood vessel. For instructions on handling of the medicinal product before administration, see section 6.6 of the Summary of Product Characteristics. (MSD (UK) Ltd, 2026)

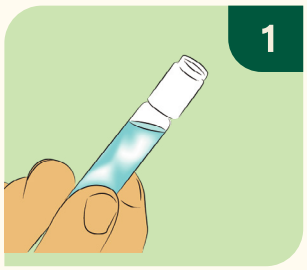
Shelf life

36 months
ENFLONSIA may be kept at room temperature (20 °C - 25 °C) for a maximum 48 hours.
After removal from the refrigerator, it must be used within 48 hours or discarded. (MSD (UK) Ltd, 2026)

Special precautions for storage

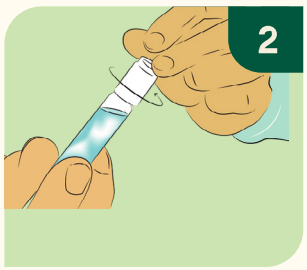
Store in a refrigerator (2 °C – 8 °C). Do not freeze. Keep the pre-filled syringe in the outer carton in order to protect from light. Do not shake. (MSD (UK) Ltd, 2026)
Packaging: 1 x 134 cm^3 pack with 2 needles (MSD (UK) Ltd, 2026)

Administration of ENFLONSIA® in 4 steps



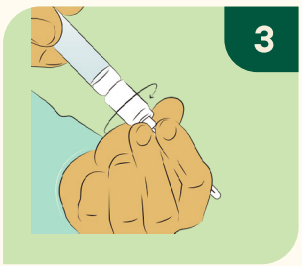
Visual inspection of the solution

Before injection, remove the box from the refrigerator and allow the pre-filled syringe to reach room temperature for about 15 minutes. Parenteral medicinal products should be inspected visually for particulate matter and discolouration prior to administration. It should not be used if particulate matter or discolouration is found.
(MSD (UK) Ltd, 2026)



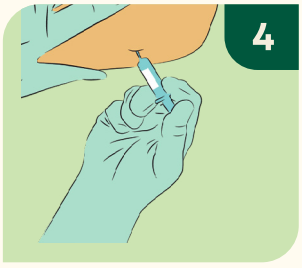
Cap removal

Hold the syringe barrel in one hand and unscrew the tip cap by twisting it counterclockwise with the other hand. Do not remove the Luer lock adaptor and the finger flange extender.
(MSD (UK) Ltd, 2026)



Preparation

Attach a sterile Luer lock needle by twisting in a clockwise direction until the needle fits securely on the syringe. If not provided, due to the viscosity of the product, use a 25 gauge or larger needle. (MSD (UK) Ltd, 2026)



Administration

Inject the entire contents of the pre-filled syringe intramuscularly, in the anterolateral aspect of the thigh. The medicinal product should not be injected in the gluteal area or area where there may be a major nerve trunk and/or blood vessel. (MSD (UK) Ltd, 2026)

Supply chain

Robust manufacturing planning and multiple mitigation measures are in place to support the reliable supply of Enflonsia throughout the RSV season.

For further medicinal product details, please see Appendix 4: Prescribing details, including contraindications, special warnings and interactions.

Part 2: Disease information

Disease burden of RSV

- RSV infects 90% of children by the age of two and is a leading cause of acute lower respiratory tract infection including pneumonia and bronchiolitis in infants and young children (NHS England, 2025)
- Infants under one year of age experience the highest rates of severe disease, and there is evidence suggesting early exposure might lead to lasting respiratory conditions (Malinczak C, Fonseca W, Hrycaj S, et al, 2024)
- Prior to the introduction of the UK RSV National Immunisation Programme, every year around 30,000 children under the age of five were hospitalised with RSV, and it caused around 30 infant deaths (NHS England, 2025)
- RSV demonstrates marked seasonality, typically peaking during the winter months, and is a major driver of paediatric hospital admissions during this period (UKHSA, 2023)
- Prior to the introduction of the RSV National Immunisation Programme, RSV in the UK led to pressure on the healthcare system accounting annually for around 467,000 GP visits and approximately £80 million in annual healthcare costs and productivity losses (Fusco F, Hocking L, and Stockwell S, et al, 2022)
- Most RSV admissions happen to full-term children without underlying risk factors (UKHSA, 2026)

High-risk populations

- Certain infants are at high risk of severe RSV infection (UKHSA, 2026)
- Preterm infants and those with underlying medical conditions including bronchopulmonary dysplasia (BPD) and congenital heart disease (CHD) are especially vulnerable (UKHSA, 2026)
- Babies born prematurely are three times more likely to need hospital admission due to RSV, and ten times more likely to need intensive care, compared to full-term babies (NHS England, 2025)

Part 3: Cost, Eligible Population and Funding Stream

NHS list price

£1,737.00

There is a confidential discount in place with the NHS. The size of the discount is confidential and can be accessed by the appropriate pharmacist within the trusts.

Eligible population

It is estimated that in the UK, around 9,000 infants per year are expected to be eligible for RSV monoclonal antibody immunisation (NHS England, 2025)

Funding stream

Access for clesrovimab will be provided through NHS frameworks, and in England, any patients that receive clesrovimab must be registered via Blueteq and meet the clinical criteria on the registration form.

Appendix 1: CLEVER (study 004)

The efficacy and safety of clesrovimab were evaluated in preterm and full-term infants in the clinical studies SMART and CLEVER. (MSD (UK) Ltd, 2026)

Efficacy against RSV-associated MALRI (Medically Attended Lower Respiratory Tract Infection), hospitalisation, and severe MALRI in neonates and infants entering their first RSV season (CLEVER) (MSD (UK) Ltd, 2026) (Zar et al., 2025)

CLEVER was a Phase 2b/3, randomised, double-blind placebo-controlled, multicentre study conducted in 22 countries from the Northern and Southern hemispheres to evaluate the efficacy of clesrovimab in healthy early and moderate preterm infants (≥29 to <35 weeks GA) and late preterm and full-term infants (≥35 weeks GA). Participants were randomised 2:1 to receive a 105 mg dose of clesrovimab (n=2 412, including 422 early and moderate preterm infants) or saline placebo (n=1 202, including 209 early and moderate preterm infants) by intramuscular injection.

Among participants who received clesrovimab or saline placebo, the median age of infants was 3.1 months (range: 0 to 12 months); 14.9% were ≤ 1 month of age; 34.5% were >1 to ≤3 months; 30.6% were > 3 to ≤ 6 months; 20.1% were > 6 months; and 51.1% were male. Of these participants, 17.5% were GA ≥29 to <35 weeks and 82.5% were GA ≥35 weeks. The median body weight was 5.8 kg (range: 1.6 to 11.9 kg). The racial distribution was as follows: 45.2% were White; 26.6% were Asian; 13.8% were Black or African American; 12.2% were multi-racial and 1.9% were American Indian or Alaska Native; 28.1% were of Hispanic or Latino ethnicity.

The primary endpoint was the incidence of RSV-associated MALRI characterised as cough or difficulty breathing and requiring ≥ 1 indicator of LRI (wheezing, rales/crackles) or severity (chest wall in-drawing/retractions, hypoxemia, tachypnoea, dehydration due to respiratory symptoms) through 150 days after dosing. Medically Attended (MA) includes all healthcare professional visits in settings such as outpatient clinic, clinical study site, emergency department, urgent care centre, and/or hospital. The statistical criterion for success required the lower bound of the 95% CI of efficacy to be greater than 25%.

RSV-associated hospitalisation through 150 days after dosing and RSV-associated MALRI through 180 days after dosing were also evaluated as secondary endpoints. RSV-associated hospitalisation was defined as hospitalisation for respiratory symptoms with a positive test for RSV. For RSV-associated hospitalisation through 150 days, the statistical criterion for success required the lower bound of the 95% CI of efficacy to be greater than 0%.

RSV-associated severe MALRI, a pre-specified exploratory endpoint, characterised by 1) cough or difficulty breathing and 2) severe hypoxemia or the need for supplemental oxygen or mechanical ventilatory support, was evaluated through 150 days after dosing.

All efficacy endpoints evaluated required an RSV positive RT-PCR nasopharyngeal (NP) sample.

Table 2 displays the efficacy results for RSV-associated disease endpoints, in order of increasing severity, in preterm and full-term infants from Days 1 through 150 post-dose.

Table 2: Incidence of RSV-associated disease in preterm and full-term infants Days 1 through 150 Post-dose (CLEVER) (MSD (UK) Ltd, 2026)

	Number of cases	Incidence rate over 5 months	Number of cases	Incidence rate over 5 months	Efficacy (95% CI)*
MALRI (requiring ≥1 indicator of LRI or severity) **Primary endpoint**	60	0.026	74	0.065	**60.4% (44.1, 71.9)†** **Absolute risk reduction: 3.9% difference in incidence rate** (Zar et al., 2025)
Hospitalisation‡ **Secondary endpoint**	9	0.004	28	0.024	**84.2% (66.6, 92.6)†** **Absolute risk reduction: 2% difference in incidence rate** (Zar et al., 2025)
Severe MALRI **Exploratory efficacy endpoint, not multiplicity controlled**	2	0.001	12	0.01	**91.7% (62.9, 98.1)** **Absolute risk reduction: 0.9% difference in incidence rate** (Zar et al., 2025)

n=Number of participants eligible for inclusion in the full analysis set population.

* Based on relative risk reduction vs placebo. Estimate and 95% CI of efficacy were estimated from the modified Poisson regression with robust variance method.

†Pre-specified multiplicity controlled; p-value < 0.001

‡An exploratory analysis evaluated RSV-associated LRI hospitalisation characterised by cough or difficulty breathing and requiring ≥1 indicator of LRI or severity in hospitalised infants with an RSV positive RT PCR NP sample (5 cases/2398 in the clesrovimab arm and 27 cases/1201 in the placebo arm; endpoint not multiplicity controlled). The estimated efficacy was 90.9% (95% CI: 76.2, 96.5).

Subgroup analyses of the primary efficacy endpoint of RSV-associated MALRI by gestational age, chronological age, body weight, sex, race and region showed results consistent with the overall population.(MSD (UK) Ltd, 2026)

Duration of protection

Based on clinical efficacy data from CLEVER, the duration of protection offered by a single dose of clesrovimab could extend through 6 months but the observation is limited by a low event incidence that occurred after 5 months post-dose. (Zar et al., 2025)

Established and consistent safety profile across infant populations in CLEVER

The most frequent adverse reactions were injection-site pain (6.5%), injection-site erythema (4.4%), injection-site swelling (3.2%) and rash (0.5%). (Zar et al., 2025)

Tabulated list of adverse events (MSD (UK) Ltd, 2026)

Table 3 presents the adverse events reported in 2 409 preterm and full-term infants (GA ≥29 weeks) who received clesrovimab.

Adverse events reported with clesrovimab are listed by MedDRA system organ class and in decreasing order of frequency. Frequencies are defined as very common (≥ 1/10), common (≥1/100 to <1/10), uncommon (≥1/1 000 to <1/100), rare (≥1/10 000 to <1/1 000), and very rare (<1/10 000) and not known (cannot be estimated from available data).

Table 3: Adverse events

System organ class	Adverse event	Frequency
Skin and subcutaneous tissue disorders	Rash*	Common
	Urticaria	Uncommon
General disorders and administration site conditions	Injection-site pain†	Common
	Injection-site erythema†	Common
	Injection-site swelling†	Common

*Rash was defined by the following grouped preferred terms occurring within 14 days post-dose: rash, rash erythematous, rash papular, rash maculo-papular, rash vesicular, dermatitis allergic, and drug eruption
†Solicited on Day 1 through Day 5 post-dose

Appendix 2: SMART (study 007)

The efficacy and safety of clesrovimab were evaluated in preterm and full-term infants in the clinical studies SMART and CLEVER. (MSD (UK) Ltd, 2026)

Interim safety results indicate ENFLONSIA® is comparable to palivizumab in infants at high risk of severe RSV disease; SMART (Study 007) (MSD (UK) Ltd, 2026)

SMART is a phase 3, randomised, partially blind, palivizumab controlled, multicentre study conducted in 27 countries from the Northern and Southern hemispheres to evaluate the safety (primary endpoint), efficacy (secondary endpoint) and pharmacokinetics of clesrovimab in early (<29 weeks GA) or moderate preterm infants (≥29 to ≤35 weeks GA), and infants with chronic lung disease of prematurity or congenital heart disease of any GA, who are at increased risk for severe RSV disease entering in their first RSV season. Participants were randomised to receive clesrovimab (n=446, including 176 infants with chronic lung disease (CLD) of prematurity or haemodynamically significant congenital heart disease (CHD) and 270 early or moderate preterm infants (≤35 weeks GA) without CLD of prematurity or CHD), or palivizumab (n=450, including 175 infants with CLD of prematurity or CHD and 275 early or moderate preterm infants (≤35 weeks GA) without CLD of prematurity or CHD) by intramuscular injection. Participants randomised to clesrovimab received a single 105 mg dose on Day 1 followed by a dose of placebo one month later; palivizumab was administered on Day 1 and every month thereafter for a total of 3 to 5 doses of 15 mg/kg.

Among participants who received clesrovimab or palivizumab, the median age of infants was 2.5 months (range: 0 to 12 months); 14.3% were ≤1 month of age; 44.3% were >1 to ≤3 months; 30.6% were > 3 to ≤ 6 months; 10.8% were >6 months; and 49.8% were male. Of these participants, 27.9% had CLD, 11.3% had CHD, 5.6% were GA less than 29 weeks with neither CLD nor CHD and 55.2% were GA greater than or equal to 29 weeks with neither CLD nor CHD. The median body weight was 3.3 kg (range: 1.1 to 9.6 kg). The racial distribution was as follows: 52.2% were White; 18.1% were Asian; 15.4% were Black or African American; 12.2% were multi-racial, and 1.3% were American Indian or Alaska Native; 31.7% were of Hispanic or Latino ethnicity.

Most adverse events were mild or moderate.

Table 4: Adverse Events (Zar et al., 2025)

Adverse events reported in preterm (GA ≤35 weeks) infants or those with CLD of prematurity or haemodynamically significant CHD in the SMART [Study 007] trial, (n=896)			
Adverse Events	**ENFLONSIA® (n=445)**	**Palivizumab (n=450)**	**Estimated difference (95% CI)***
	Number of infants (percent)		**Percentage points**
Drug-related†	**141 (31.7)**	**163 (36.2)**	**-4.5 (-10.7 to 1.7)**
Serious adverse events			
Drug-related†	**0**	**2 (0.4)**	**-0.4 (-1.6 to 0.4)**
Adverse events of special interest			
Anaphylaxis or hypersensitivity	**0**	**0**	**0.0 (-0.8 to 0.9)**
Rash	**3 (0.7)**	**1 (0.2)**	**0.5 (-0.6 to 1.8)**

*Differences and CIs were estimated with the Miettinen and Nurminen method.
†Relatedness to treatment was determined by the investigator.

Efficacy against RSV-associated MALRI and hospitalisation in infants at increased risk of severe RSV disease entering their first RSV season (SMART) (MSD (UK) Ltd, 2026)

The efficacy of clesrovimab in infants at increased risk for severe RSV disease was established by extrapolation of efficacy of clesrovimab from CLEVER to SMART based on pharmacokinetic exposure (see section 5.2 of the Summary of Product Characteristics). In SMART, the incidence rate of RSV-associated MALRI (requiring ≥1 indicator of LRI or severity) through 150 days after dosing was 3.6% (95% CI: 2.0, 6.0; 14 cases/443 in analysis set) in the clesrovimab arm and 3.0% (95% CI: 1.6, 5.3; 12 cases/437 in the analysis set) in the palivizumab arm. The incidence rate of RSV-associated hospitalisation through 150 days after dosing was 1.3% (95% CI: 0.4, 3.0; 5 cases/443 in analysis set) in the clesrovimab arm and 1.5% (95% CI: 0.6, 3.3; 6 cases/437 in analysis set) in the palivizumab arm. (MSD (UK Ltd, 2026)

Overdose

There is no specific treatment for an overdose with clesrovimab. In the event of an overdose, the individual should be monitored for the occurrence of adverse reactions and provided with symptomatic treatment as appropriate. (MSD (UK) Ltd, 2026)

Appendix 3: Mechanism of action

Pharmacodynamic properties

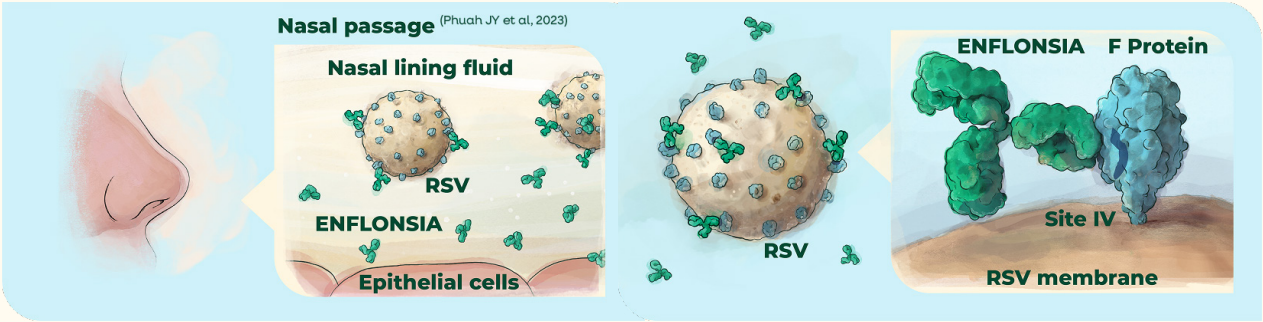
Pharmacotherapeutic group: Immune sera and immunoglobulins, antiviral monoclonal antibodies, ATC code: J06BD10

Mechanism of action

Clesrovimab is a fully human immunoglobulin G1 kappa (IgG1κ) neutralising monoclonal antibody with a triple amino acid substitution (YTE) 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 (F) protein to prevent viral entry into cells.

Clesrovimab binds to a conserved epitope on antigenic site IV on the fusion F protein. Clesrovimab binds to RSV pre-fusion F glycoprotein and post-fusion F glycoprotein with equilibrium dissociation constant values (KD) of 71 pM and 480 pM, respectively.

RSV A and B isolates were equipotently neutralised by clesrovimab in vitro. (MSD (UK) Ltd, 2026)



Appendix 4: Prescribing details, including contraindications, special warnings, and interactions

For full prescribing information, please refer to the Summary of Product Characteristics.

Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in the Summary of Product Characteristics. (MSD (UK) Ltd, 2026)

Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Hypersensitivity including anaphylaxis

If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, appropriate treatment and/or supportive therapy should be initiated.

Individuals with thrombocytopenia and coagulation disorders

As with any other intramuscular injections, clesrovimab should be given with caution to infants with thrombocytopenia or any coagulation disorder, because bleeding or bruising may occur following an intramuscular administration in these individuals.

Excipients with known effect

This medicinal product contains 0.14 mg of polysorbate 80 per dose. Polysorbates may cause allergic reactions. (MSD (UK) Ltd, 2026)

Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed. Monoclonal antibodies do not typically have significant interaction potential, as they do not directly affect cytochrome P450 enzymes and are not substrates of hepatic or renal transporters. Indirect effects on cytochrome P450 enzymes are unlikely as the target of clesrovimab is an exogenous virus.

Clesrovimab does not interfere with reverse transcriptase polymerase chain reaction (RT-PCR) or rapid antigen detection RSV diagnostic assays that employ commercially available antibodies targeting antigenic site 0, I, II, III, or V on the RSV fusion (F) protein. For rapid antigen detection RSV diagnostic assay results which are negative when clinical observations are consistent with RSV infection, it is recommended to confirm using an RT-PCR-based assay.

Concomitant administration with childhood vaccines

Since clesrovimab is a monoclonal antibody, a passive immunisation specific for RSV, it is not expected to interfere with the active immune response to co-administered vaccines.

There is limited experience of co-administration with vaccines. In clinical studies, when clesrovimab was given concomitantly with routine childhood vaccines, the safety profile of the co-administered regimen was similar to the safety profile when clesrovimab and childhood vaccines were administered alone. Clesrovimab can be given concomitantly with childhood vaccines.

When clesrovimab is administered concomitantly with injectable vaccines, it should be given using a separate syringe and at a different injection-site. It should not be mixed with any vaccines or medications in the same syringe or vial (see section 6.2 of the Summary of Product Characteristics).

There are no data regarding substitution of clesrovimab for palivizumab once prophylaxis treatment is initiated with palivizumab for the RSV season. (MSD (UK) Ltd, 2026)

References

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