Enflonsia (clesrovimab-cfor) approved to prevent RSV in newborns and infants

22.4.2026 - | Her Majesty's Revenue and Customs

As with any medicine, the MHRA will keep the safety and effectiveness of Enflonsia under close review.

The Medicines and Healthcare products Regulatory Agency (MHRA) has today, 22 April 2026 approved the medicine Enflonsia (clesrovimab-cfor) for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in newborns and infants up to 12 months of age throughout their first RSV season.

RSV is a common and highly contagious seasonal illness that usually causes symptoms similar to the common cold and can also affect the lungs. Almost all children get an RSV infection before they are two years old. RSV can lead to life-threatening pneumonia and infant bronchiolitis (a lung infection).

The active ingredient in Enflonsia, clesrovimab, is an antibody (a protein that helps the body to fight harmful germs) that helps prevent lung disease caused by RSV.

Julian Beach, MHRA Executive Director, Healthcare Quality and Access, said:

“It’s important that we do our best to protect our newborn babies and infants especially throughout RSV season.

“Part of this is enabling access to high quality, safe and effective medical products are key priorities for us.

“As with any medicine, the MHRA will continue to closely monitor the safety and effectiveness of clesrovimab.”

Clesrovimab is a single injection administered once by a healthcare professional.

The most common side effects associated with this medicine include pain, swelling, redness, or rashes at the injection site.

Anyone who suspects their child is having a side effect from this medicine is encouraged to talk to their doctor, pharmacist, or nurse, and report it directly to the Yellow Card scheme, either through the website (https://yellowcard.mhra.gov.uk/) or by searching the Google Play or Apple App stores for MHRA Yellow Card.

Notes to editors

1. The new marketing authorisation was granted on 22 April 2026 to Merck Sharp Dohme (UK) Limited.

2. More information can be found in the Summary of Product Characteristics and Patient Information leaflets which will be published on the MHRA Products website within 7 days of approval.

3. For more information about RSV, visit: https://www.nhs.uk/conditions/respiratory-syncytial-virus-rsv/

4. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.

5. The MHRA is an executive agency of the Department of Health and Social Care.

6. For media enquiries, please contact the newscentre@mhra.gov.uk, or call on 020 3080 7651.

https://www.gov.uk/government/news/enflonsia-clesrovimab-cfor-approved-to-prevent-rsv-in-newborns-and-infants