



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Enflonsia (*clesrovimab*)

An overview of Enflonsia and why it is authorised in the EU

What is Enflonsia and what is it used for?

Enflonsia is a medicine used to prevent lower respiratory tract disease (diseases of the lungs such as bronchiolitis or pneumonia) caused by respiratory syncytial virus (RSV) in newborns and infants up to 12 months of age during their first RSV season. RSV season is the time of the year when RSV infections are most common, usually from autumn to spring.

Enflonsia contains the active substance clesrovimab.

How is Enflonsia used?

Enflonsia can only be obtained with a prescription and should be used according to official recommendations.

Enflonsia is given as a single injection into the thigh muscle. It is given from birth to babies born during the RSV season or before the babies' first RSV season starts.

For more information about using Enflonsia, see the package leaflet or contact your doctor or pharmacist.

How does Enflonsia work?

The active substance in Enflonsia, clesrovimab, is a monoclonal antibody, a type of protein designed to recognise and attach to a specific protein. Clesrovimab attaches to the 'F protein' on the surface of RSV, which prevents the virus from entering the body's cells. This helps prevent lower respiratory tract disease caused by RSV, such as bronchiolitis or pneumonia.

What benefits of Enflonsia have been shown in studies?

Enflonsia was shown to be effective at preventing lower respiratory tract disease caused by RSV in two main studies in newborns and infants during their first RSV season.

One study compared Enflonsia with placebo (a dummy treatment) in 3,632 healthy infants up to 12 months of age, born prematurely (between 29 and before 35 weeks of pregnancy) or at late pre-term/full term (at 35 weeks of pregnancy or later). In the 150 days after receiving treatment during

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their first RSV season, 2.5% of infants (60 out of 2,398) who received Enflonsia developed lower respiratory tract disease caused by RSV that required medical attention compared with 6.2% (74 out of 1,201) of those given placebo. Infants were considered to have lower respiratory tract disease caused by RSV when a test showed they were infected with the virus and they had symptoms such as cough or difficulty breathing, as well as more serious signs, including wheezing or crackling sounds in the lungs.

A second study compared Enflonsia with palivizumab (another medicine used to prevent lower respiratory tract disease caused by RSV) in 901 infants who were either born prematurely (at 35 weeks of pregnancy or earlier) or born at full term but had heart or lung disease which put them at higher risk of lower respiratory tract disease caused by RSV. In the 150 days after receiving treatment during their first RSV season, 3.2% of infants (14 out of 443) who received Enflonsia had lower respiratory tract disease caused by RSV that required medical attention, similar to the 2.7% of infants (12 out of 437) given palivizumab.

What are the risks associated with Enflonsia?

For the full list of side effects and restrictions with Enflonsia, see the package leaflet.

The most common side effects with Enflonsia (which may affect up to 1 in 10 people) include pain, redness and swelling at the injection site, and rash.

Why is Enflonsia authorised in the EU?

Enflonsia was shown to be effective at preventing lower respiratory tract disease caused by RSV in newborns and infants during their first RSV season. There are uncertainties regarding the use of Enflonsia in infants with a low body weight (less than 1.1 kg) due to the lack of data in this population. Regarding safety, side effects were mild to moderate and considered acceptable. The European Medicines Agency therefore decided that Enflonsia's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Enflonsia?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Enflonsia have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Enflonsia are continuously monitored. Suspected side effects reported with Enflonsia are carefully evaluated and any necessary action taken to protect patients.

Other information about Enflonsia

Enflonsia received a marketing authorisation valid throughout the EU on 15 April 2026.

Further information on Enflonsia can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/enflonsia.

This overview was last updated in 04-2026.