swissmedic

Summary report on authorisation dated 10 July 2026

Enflonsia® (active substance: clesrovimab)

Authorisation in Switzerland: 22 January 2026

Solution for injection in pre-filled syringe for the prevention of lower respiratory tract disease caused by the respiratory syncytial virus (RSV) in neonates and infants born before or during their first RSV season.

About the medicinal product

Enflonsia is a medicinal product that helps prevent lower respiratory tract disease caused by the respiratory syncytial virus (RSV).

RSV is a common, very infectious virus that generally causes mild respiratory symptoms similar to a cold.

RSV infections are among the most frequent causes of illnesses of the lower respiratory tract in infants and toddlers. RSV infections are generally seasonal.

The associated diseases can be particularly severe in infants up to 6 months of age, adults 65 years of age and older, people with chronic heart or lung diseases, and immunocompromised individuals. In neonates, infants and toddlers, RSV infection can trigger bronchiolitis (inflammation of the small airways in the lung) or pneumonia.

Enflonsia contains the active substance clesrovimab.

Enflonsia was authorised under the Access Consortium.

The Access Consortium is a joint work sharing initiative between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA), and Switzerland (Swissmedic). It coordinates the joint assessment of medicinal products that have been submitted for authorisation in at least two of the five countries.

The authorisation application for Enflonsia was submitted to the drug regulatory authorities in Australia, Canada, Singapore and Switzerland. Each authority assessed part of the application. They then exchanged and discussed the assessments. At the end of the process, each authority makes its own decision on authorisation.
Swissmedic considered the foreign authorities' assessments when deciding to authorise the medicinal product.
Since the preconditions for a full SwissPAR (Swiss Public Assessment Report) and a resulting Summary report on authorisation are not met, Swissmedic refers to the assess-

ments of the participating foreign authorities. Further information on the Access joint initiative can be found on the Swissmedic website: Access Consortium (swissmedic.ch).

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Enflonsia®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.