24 July 2025
EMADOC-1700519818-2313919
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

mResvia

Respiratory Syncytial Virus (RSV) mRNA vaccine

On 24 July 2025 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product mResvia. The marketing authorisation holder for this medicinal product is Moderna Biotech Spain S.L.

The CHMP adopted an extension to the existing indication to extend the use of mResvia to adults from 18 through 59 years of age who are at increased risk for lower respiratory tract disease caused by RSV. The full indications for mResvia will therefore be as follows:[2]

> mRESVIA is indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by Respiratory Syncytial Virus **(RSV)** in:
>
> - adults 60 years of age and older;
> - **adults 18 through 59 years of age who are at increased risk for LRTD caused by RSV.**
>
> The use of this vaccine should be in accordance with official recommendations.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union