11 December 2025
EMADOC-1700519818-2676032
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Arexvy

Respiratory syncytial virus (RSV) vaccine (recombinant, adjuvanted)

On 11 December 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 Arexvy. The marketing authorisation holder for this medicinal product is GlaxoSmithKline Biologicals SA.

The CHMP adopted an extension to the existing indication, as follows:[2]

> Arexvy is indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in~~:~~
>
> adults **18**~~60~~ years of age and older**.**~~;~~
>
> ~~• adults 50 through 59 years of age who are at increased risk for RSV disease.~~
>
> The use of this vaccine should be in accordance with official recommendations.

For information, the full indication for Arexvy will be:

> Arexvy is indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in adults 18 years of age and older.
>
> 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) 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, removed text as strikethrough

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