



25 July 2024
EMA/CHMP/304362/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Arexvy

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

On 25 July 2024, 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 S.A.

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 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.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR) and made available 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

