27 June 2024
EMA/CHMP/37430/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Beyfortus

nirsevimab

On 27 June 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 Beyfortus. The marketing authorisation holder for this medicinal product is Sanofi Winthrop Industrie.

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

> Beyfortus is indicated for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in**:**
>
> **i.** **N**~~n~~eonates and infants during their first RSV season.
>
> **ii.** **Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season (see section 5.1).**
>
> Beyfortus should be used 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 will be 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, 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