15 September 2022
EMA/CHMP/647784/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Beyfortus

nirsevimab

On 15 September 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Beyfortus, intended for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in newborns and infants.

Beyfortus was reviewed under EMA's accelerated assessment programme.

The applicant for this medicinal product is AstraZeneca AB.

Beyfortus will be available as a 50 mg and 100 mg solution for injection. The active substance of Beyfortus is nirsevimab, an antiviral monoclonal antibody (ATC code: J06BD08) which binds to the RSV F (fusion) protein. This locks the protein in the pre-fusion conformation, thereby inhibiting entry of free virions into cells, as well as inhibiting spread of cell-associated virus by cell fusion.

The benefits of Beyfortus are the prevention of medically attended lower respiratory tract infection caused by RSV, predominantly bronchiolitis and pneumonia, in term and preterm infants entering their first RSV season. The most common side effects are rash, pyrexia and injection site reactions.

The full indication is:

> Beyfortus is indicated for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in neonates and infants during their first RSV season.
>
> Beyfortus should be used in accordance with official recommendations.

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

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