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Beyfortus (*nirsevimab*)

An overview of Beyfortus and why it is authorised in the EU

What is Beyfortus and what is it used for?

Beyfortus is a medicine used to prevent serious lower respiratory tract (lung) disease caused by respiratory syncytial virus (RSV) in newborns and children during their first RSV season.

Beyfortus contains the active substance nirsevimab.

How is Beyfortus used?

The medicine can only be obtained with a prescription.

Beyfortus is given as a single injection into the thigh muscle. It is given once before the RSV season starts or at birth for infants born during the RSV season. The recommended dose is 50 mg for children weighing less than 5 kg and 100 mg for children weighing 5 kg or more.

For more information about using Beyfortus, see the package leaflet or contact your healthcare provider.

How does Beyfortus work?

The active substance in Beyfortus, nirsevimab, is a monoclonal antibody. A monoclonal antibody is a type of protein that has been designed to recognise and attach to a specific structure (called an antigen). Nirsevimab attaches to a protein called 'F protein' on the surface of RSV. When nirsevimab is attached to this protein, the virus becomes unable to enter the body's cells, especially those in the lungs. This helps to prevent RSV infection.

What benefits of Beyfortus have been shown in studies?

Beyfortus was shown to be effective at reducing lower respiratory tract disease caused by RSV in three main studies.

One study compared Beyfortus with placebo (a dummy treatment) in 1,490 healthy children born prematurely and at term (at 35 weeks gestation or more). After receiving Beyfortus during their first

[1] Correction of percentage in section "what benefits of Beyfortus have been shown in studies?": 2.6 % has been amended to 5% (25 out of 496)

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RSV season, 1.2% of children (12 out of 994) developed RSV-induced lung disease that required medical attention compared with 5% (25 out of 496) in the placebo group.

Similar results were seen in a second study comparing Beyfortus with placebo in 1,453 children born five or more weeks prematurely (between 29 and 35 weeks gestation). After receiving Beyfortus during their first RSV season, 2.6% of children (25 out of 969) developed RSV-induced lung disease that required medical attention compared with 9.5% (46 out of 484) in the placebo group.

A third study compared Beyfortus with palivizumab (another medicine to prevent RSV-induced lung disease) in children who were either born prematurely, or born at full term but had heart or lung disease which put them at risk of RSV-induced lung disease. After receiving Beyfortus, 4 children (out of 616) developed RSV-induced lung disease that required medical attention compared with 3 children (out of 309) in the group who had palivizumab.

What are the risks associated with Beyfortus?

The most common side effects with Beyfortus (which may affect up to 1 in 100 people) are rash occurring within 14 days after injection, and fever and injection site reactions occurring within 7 days after injection.

For the full list of side effects and restrictions with Beyfortus, see the package leaflet.

Why is Beyfortus authorised in the EU?

Beyfortus was shown to be effective at preventing RSV-induced lung disease that required medical attention. In terms of safety, its side effects are considered manageable and in line with what can be expected of this class of medicines. The European Medicines Agency decided that Beyfortus's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Beyfortus?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Beyfortus have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Beyfortus are continuously monitored. Suspected side effects reported with Beyfortus are carefully evaluated and any necessary action taken to protect patients.

Other information about Beyfortus

Beyfortus received a marketing authorisation valid throughout the EU on 31 October 2022.

Further information on Beyfortus can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/beyfortus