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Beyfortus® (active substance: nirsevimab)

First authorisation in Switzerland: 22 December 2023

Medicinal product for the prevention of lower respiratory tract disease caused by the respiratory syncytial virus (RSV).

About the medicinal product

The medicinal product Beyfortus is used for the prevention of lower respiratory tract disease caused by the respiratory syncytial virus (RSV) in:

- neonates and infants entering or during their first RSV season.
- toddlers up to 24 months of age who remain vulnerable to severe RSV disease in their second RSV season.

The medicinal product Beyfortus should be used in accordance with the official recommendations.

RSV is a respiratory tract virus that usually causes mild, cold-like symptoms. However, in neonates, infants and toddlers, the virus can trigger severe disease, leading to pneumonia or bronchiolitis (inflammation of the small airways in the lung).

Infections with RSV are among the most frequent causes of illnesses of the lower respiratory tract in infants and toddlers. Outbreaks of RSV infections are usually seasonal. Almost all infants and toddlers up to the age of 2 become infected with RSV, and reinfection is common.

Mode of action

Beyfortus contains the active substance nirsevimab. Nirsevimab is a long-acting monoclonal antibody produced by recombinant DNA technology[1].

The monoclonal antibody nirsevimab is a protein that can bind to other proteins. Nirsevimab binds to the binding site for the RSV-A and RSV-B subtypes of the infectious virus, thereby neutralising RSV.

By blocking the virus at the binding site, RSV is also unable to enter the body's cells.

With this mechanism of action, Beyfortus helps the body defend itself against RSV and thus prevent a lower respiratory tract disease caused by RSV.

[1] Recombinant DNA technology: a genetic engineering process

Administration

Beyfortus is a prescription-only medicine.

Beyfortus is available as a solution for injection in pre-filled syringes with 50 mg in 0.5 ml and 100 mg in 1 ml (100 mg/ml).

The recommended dose for infants weighing less than 5 kg is a single dose of 50 mg. For infants weighing 5 kg or more, the recommended single dose is 100 mg.

Beyfortus should only be administered by a healthcare professional as an intramuscular injection, preferably in the thigh.

For toddlers who remain vulnerable to severe RSV disease after the first immunisation with Beyfortus, the paediatrician will recommend a further dose in the second RSV season. The recommended dose is a single dose of 200 mg, administered as two intramuscular injections (2 x 100 mg).

Efficacy

The efficacy of Beyfortus was investigated in 2 studies (D5290C00003 and MELODY) in, respectively, 1453 and 1490 infants and toddlers overall. Both studies showed that Beyfortus, containing the active substance nirsevimab, provides protection with an efficacy of over 70 % against a lower respiratory tract disease caused by RSV.

These studies also showed that the risk of hospitalisation of infants and toddlers infected with RSV was decreased.

The clinical trials demonstrated that Beyfortus protects against RSV-A and RSV-B.

As shown by the clinical data, the protection afforded by the administration of Beyfortus lasts at least 5 months.

Precautions, undesirable effects, & risks

Beyfortus must not be used in those who are hypersensitive to the active substance or any of the excipients.

Like all monoclonal antibodies, Beyfortus can also produce side effects, although not necessarily in everyone. Skin rashes, reactions at the injection site, or fever can occur occasionally.

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

The human respiratory syncytial virus (RSV) is the most common cause of acute lower respiratory tract infections in infants and toddlers.

At present, the treatment options for RSV disease are mainly supportive.

The studies showed that Beyfortus protects neonates and infants in their first RSV season and toddlers up to 24 months of age who also remain vulnerable to severe RSV disease in the second RSV season from a lower respiratory tract disease caused by RSV.

Taking all the risks and precautions into account, and based on the available data, the benefits of Beyfortus outweigh the risks. Swissmedic has therefore authorised the me-

dicinal product Beyfortus, containing the active substance nirsevimab, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Beyfortus®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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