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EPAR summary for the public

Synagis
palivizumab

This is a summary of the European public assessment report (EPAR) for Synagis. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Synagis.

What is Synagis?

Synagis is a powder and solvent that are made up into a solution for injection. It contains the active substance palivizumab.

What is Synagis used for?

Synagis is used to prevent serious lower respiratory tract (lung) disease caused by respiratory syncytial virus (RSV) that would require hospitalisation. It is used in the following groups of children, who are at high risk for this disease:

- children who are less than six months old and were born five or more weeks prematurely (at 35 weeks gestation or less);
- children who are less than two years of age and have had treatment for bronchopulmonary dysplasia (abnormal lung tissue, usually seen in babies born prematurely) within the last six months;
- children who are less than two years of age and were born with a serious heart disease.

The medicine can only be obtained with a prescription.

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How is Synagis used?

Synagis is given once a month when there is a risk of RSV infection in the community: in the northern hemisphere, this is from November to April. If possible, the first dose should be given before this season starts. Patients generally receive a total of five monthly injections into the thigh muscle.

How does Synagis work?

The active substance in Synagis, palivizumab, is a monoclonal antibody. A monoclonal antibody is an antibody (a type of protein) that has been designed to recognise and attach to a specific structure (called an antigen). Palivizumab has been designed to attach to a protein called 'fusion protein A' on the surface of RSV. When palivizumab 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.

How has Synagis been studied?

The main study of Synagis was carried out in 1,502 high-risk children and compared Synagis with placebo (a dummy treatment) during one RSV season. Another study was also carried out comparing Synagis with placebo in 1,287 children who were born with heart disease. In both studies, the main measure of effectiveness was the number of children who had to be admitted to hospital because of RSV infection.The effects of Synagis were first tested in experimental models before being studied in humans.

What benefit has Synagis shown during the studies?

Synagis was more effective than placebo in reducing RSV-related hospitalisations: 5% of the children who received Synagis were admitted to hospital for RSV infection during the study, compared with 11% of those who received placebo. This was a reduction of 55%. In children born with heart disease, there was a reduction of 45%.

What is the risk associated with Synagis?

The most common side effects with Synagis (seen in between 1 and 10 patients in 100) are fever and rash. For the full list of all side effects reported with Synagis, see the package leaflet.

Synagis must not be used in people who are hypersensitive (allergic) to palivizumab, any of the other ingredients or other 'humanised' monoclonal antibodies.

Why has Synagis been approved?

The CHMP decided that Synagis's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Synagis

The European Commission granted a marketing authorisation valid throughout the European Union for Synagis on 13 August 1999.

The full EPAR for Synagis can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Synagis, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2013.