Palivizumab

Palivizumab (brand name **Synagis** which is manufactured by MedImmune) is a monoclonal antibody produced by recombinant DNA technology. It is used in the prevention of respiratory syncytial virus (RSV) infections. It is recommended for infants that are high-risk because of prematurity or other medical problems such as congenital heart disease.

Palivizumab is a humanized monoclonal antibody (IgG) directed against an epitope in the A antigenic site of the F protein of RSV. In two Phase III clinical trials in the pediatric population, palivizumab reduced the risk of hospitalization due to RSV infection by 55% and 45%. Palivizumab is dosed once a month via intramuscular (IM) injection, to be administered throughout the duration of the RSV season.[1]

Palivizumab targets the fusion protein of RSV,[2] inhibiting its entry into the cell and thereby preventing infection.

1 Recommendations for use

Palivizumab was licensed in June 1998 by the Food and Drug Administration for the reduction of serious lower respiratory tract infection caused by respiratory syncytial virus in children at increased risk of severe disease.[3] Since that time, the American Academy of Pediatrics has updated its guidance for the use of palivizumab 4 times as additional data became available to provide a better understanding of infants and young children at greatest risk of hospitalization attributable to RSV infection. The updated recommendations in this policy statement reflect new information regarding the seasonality of RSV circulation, palivizumab pharmacokinetics, the changing incidence of bronchiolitis hospitalizations, the effect of gestational age and other risk factors on RSV hospitalization rates, the mortality of children hospitalized with RSV infection, the effect of prophylaxis on wheezing, and palivizumab-resistant RSV isolates. This policy statement updates and replaces the recommendations found in the 2012 Red Book. Pediatrics 2014;134:415–420[4]

Infants younger than one year with bronchopulmonary dysplasia (i.e. who were born at <32 weeks gestation and required supplemental oxygen for the first 28 days after birth) and infants younger than two years with bronchopulmonary dysplasia who required medical therapy (e.g. supplemental oxygen, glucocorticoids, diuretics) within six months of the anticipated RSV season are recommended to use palivizumab as prophylaxis. Also, infants younger than one year who were born at <29 weeks (i.e. ≤28 weeks, 6 days) of gestation are recommended to use palivizumab.

Other potential target groups for palivizumab prophylaxis include:[5]

- Infants younger than one year of age with hemodynamically significant congenital heart disease.
- Children younger than one year of age with neuromuscular disorders impairing the ability to clear secretions from the upper airways or pulmonary abnormalities.
- Children younger than two years of age who are immunocompromised (e.g. those with severe combined immunodeficiency; those younger than two years of age who have undergone lung transplantation or hematopoietic stem cell transplantation) during the RSV season.
- Children with Down syndrome who have additional risk factors for lower respiratory tract infections.
- Alaska native and American Indian infants.

Decisions regarding palivizumab prophylaxis for children in these groups should be made on a case-by-case basis.

2 Side effects

Palivizumab use may cause side effects, which include, but are not limited to:[6]

- Sore throat
- Runny nose
- Redness or irritation at injection site
- Vomiting
- Diarrhea

Some more serious side effects include:

- Severe skin rash
- Itching

- Hives (urticaria)
- Difficulty breathing

Patients experiencing any of the serious symptoms are advised to consult a health care provider immediately.

3 References

[1] http://www.accessdata.fda.gov/drugsatfda_docs/label/2002/palimed102302LB.pdf

[2] Levinson, Wilson. "Medical Microbiology and Immunology, 8th ed." Lange: 2004. p. 430.

[3] Committee, Committee on Infectious Diseases and Bronchiolitis Guidelines (2014-07-01). "Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection". *Pediatrics*. **134**: peds.2014–1665. doi:10.1542/peds.2014-1665. ISSN 0031-4005. PMID 25070315.

[4] "Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection". *PEDIATRICS*. **134**: 415–420. doi:10.1542/peds.2014-1665. PMID 25070315.

[5] Newborn, Committee on Infectious Diseases and Committee on Fetus and (2003-12-01). "Revised Indications for the Use of Palivizumab and Respiratory Syncytial Virus Immune Globulin Intravenous for the Prevention of Respiratory Syncytial Virus Infections". *Pediatrics*. **112** (6): 1442–1446. doi:10.1542/peds.112.6.1442. ISSN 0031-4005. PMID 14654627.

[6] "Palivizumab Injection: MedlinePlus Drug Information". *www.nlm.nih.gov*. Retrieved 2016-01-30.

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