

ABOUT SYNAGIS[®], (palivizumab)

- Synagis[®], (palivizumab), manufactured by MedImmune, Inc., is indicated for the prevention of lower respiratory tract disease caused by Respiratory Syncytial Virus (RSV) in pediatric patients at high-risk for RSV disease. Synagis has been shown to be safe and effective in reducing RSV hospitalization in children with a history of prematurity (babies born at least five weeks early), with or without bronchopulmonary dysplasia (BPD).
- In clinical studies, Synagis has been shown to be safe and generally well tolerated. RSV hospitalizations occurred among 53 of 500 (10.6%) patients in the placebo group (children not receiving Synagis) and 48 of 1002 (4.8%) patients in the Synagis group (children receiving medication), a 55% reduction ($p < 0.001$).¹
- Synagis can be easily administered in the doctor's office, at home or in the hospital. Synagis is given by intramuscular injection once a month, before and during the RSV season (generally, early fall through spring).
- Synagis is the only humanized monoclonal antibody for the prevention of serious RSV disease. This preventive medication is designed to bind to the RSV virus and help prevent the virus from infecting cells in the lung.
- In clinical trials, no significant differences in adverse events were reported between placebo group and Synagis group. Synagis has been used safely in thousands of babies. Adverse events with Synagis may include upper respiratory tract infection, ear infection, fever, runny nose, and very rare cases of severe allergic reactions such as anaphylaxis and hypersensitivity reactions.
- The cost of treating a child hospitalized for RSV can exceed \$70,000.² The cost of Synagis is approximately \$5,000 for one season and is often covered by insurance.

Synagis in Congenital Heart Disease (CHD)³

- In a clinical study involving children under two years of age who had hemodynamically significant CHD, children who received Synagis experienced 45 percent fewer hospitalizations due to RSV compared to children receiving placebo (a placebo is an injection with no active ingredients).
- In the same study, children receiving Synagis also experienced statistically significant fewer RSV-related hospital days and fewer days of increased oxygen use compared to children receiving placebo.
- The study also demonstrated statistically significant fewer RSV-related hospital days and fewer days of increased oxygen use in the Synagis group compared to the placebo group.

There was no significant difference in the number of children with adverse events between the two trial groups.

Important Treatment Considerations

- In both the IMpact-RSV and CHD trials, Synagis was safe and generally well-tolerated, with no significant differences in drug-related adverse events between the groups treated with Synagis or placebo.
- The adverse reactions most commonly observed in Synagis-treated patients were upper respiratory tract infection, otitis media, fever, rhinitis, rash, diarrhea, cough, vomiting, gastroenteritis, wheezing, cyanosis, and arrhythmia.

Synagis has been used safely in thousands of babies. Adverse events with Synagis may include upper respiratory tract infection, ear infection, fever, and runny nose. Very rare cases of severe allergic reactions such as anaphylaxis (<1 case per 100,000 patients) and hypersensitivity reactions have been reported. Synagis should not be used in patients with a history of a severe prior reaction to Synagis or its components.

Please see full prescribing information accompanying this welcome packet.

¹ The IMpact RSV Study Group. Palivizumab, a humanized respiratory syncytial virus monoclonal antibody, reduces hospitalization from respiratory syncytial virus infection in high-risk infants. *Pediatrics*. 1998;102:531-537.

² Marchetti A, et al. Impact of palivizumab on expected costs of RSV infection in preterm infants: potential for savings. *Clin Therapeutics*. 1999;21:752-766.

³ Feltes, TF, Cabalka, AK, Meissner, HC, et al. Palivizumab prophylaxis reduces hospitalization due to respiratory syncytial virus in young children with hemodynamically significant congenital heart disease. *The Journal of Pediatrics*. 2003; 143(4):532-540.