RSV is the #1 cause of hospitalization in babies under one year of age.

RSV can cause severe lung infection. Respiratory syncytial virus (RSV) is a common, easily spread virus. In most children, RSV causes moderate-to-severe cold-like symptoms. But for some babies, RSV can lead to serious lung infection, breathing problems and hospitalization. Babies born at 35 weeks or less, or born with heart or lung problems, are at higher risk for severe RSV disease.

Synagis® is the only FDA-approved medicine to help protect babies from severe RSV disease. Preemies are often born before they can get enough infection-fighting antibodies from their mothers. That’s where Synagis comes in. Each dose of Synagis helps protect your baby with enough RSV-fighting antibodies to last about a month.

During RSV season, Synagis is given every 28 to 30 days. RSV season usually starts in the fall and continues into the spring. That’s why your baby needs every prescribed monthly Synagis dose – even if he or she is sick or has already had RSV.

Important Safety Information About Synagis. Synagis® (palivizumab) is indicated for the prevention of serious lung infections caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease. Synagis is given as a shot, usually in the thigh muscle, each month during the RSV season. The first dose of Synagis should be given before RSV season begins. Children who develop an RSV infection while receiving Synagis should continue the monthly dosing schedule throughout the season. Synagis has been used in more than one million children in the U.S. since its introduction in 1998.

Very rare cases (<1 per 100,000 patients) of severe allergic reactions such as anaphylaxis and rare (<1 per 1,000 patients) hypersensitivity reactions have been reported with Synagis. These rare reactions may occur when any dose of Synagis is given, not just the first one. Side effects with Synagis may include upper respiratory tract infection, ear infection, fever, and runny nose. In children born with heart problems, Synagis was associated with reports of low blood oxygen levels and abnormal heart rhythms. 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 on the back of this sheet.
SYNAGIS® (PALIVIZUMAB)

DESCRIPTION: Synagis (palivizumab) is a humanized monoclonal antibody (IgG1) produced by recombinant DNA technology, directed to an epitope in the A antigenic site of the F protein of respiratory syncytial virus (RSV). Synagis is recombinant humanized antibody and contains human (86%) and murine (14%) antibody sequences. The human heavy chain gene was derived from the constant domains of human IgG1 and the variable regions of the human heavy chain gene were derived from the variable regions of the Ck gene of the variable framework regions of the V gene (C14, C21 and C22). The human light chain gene sequence was derived from the human light chain variable and constant regions of the V gene, K104 with j=4 (3). The murine sequences were derived from the predetermined framework regions of the F protein that were shown to be involved in the replication of the murine complementarily determining regions into the human antibody framework. Synagis is composed of two heavy chains and two light chains, each approximately 140,000 daltons.

Synagis is supplied as a sterile, preservative-free liquid solution at 100 mg/mL to be administered by intramuscular injection (IM). Thimerosal or other mercury containing salts are not used in the production of Synagis. The pH of Synagis is 5.5 to 6.0 and should appear slightly opalescent.

No data from clinical studies are available on overdosage. No toxicity was observed in animals following oral administration of Synagis. The clinical studies described below.

The initial study (Trial 1) of Synagis evaluated the effect of Synagis treatment on RSV hospitalization in infants who were born prematurely and over the course of their first winter. The data from this study were used to establish the recommended dosing of Synagis for this population. Synagis was administered in a dose of 15 mg/kg intramuscularly using aseptic technique, preferably in the upper anterolateral aspect of the upper thigh. The recommended dose of Synagis is 15 mg/kg for the first dose and 15 mg/kg at months 2, 3, and 4. The first dose should be administered prior to commencement of the RSV season. In the northern hemisphere, the RSV season typically commences in November and lasts through April, but may be earlier or persist later in certain communities.

In Trial 1, the incidence of anti-Synagis antibody following the fourth injection was 1.1% in the placebo group and 0.7% in the Synagis group. In pediatric patients receiving Synagis for a second season, one of the fifty-six symptomatic patients had a low level of anti-Synagis antibody in serum concentrations. Immunogenicity was not assessed in Trial 2.

In Trials 1 and 2, none of the patients tested positive for antibodies to Synagis in an ELISA assay, and are highly dependent on the sensitivity and specificity of the assay. In both trials, the observed incidence of antibody positivity in any assay is likely to be influenced by several factors including sample handling, concomitant medications, and underlying disease.

Clinical studies of Synagis in patients with congenital heart disease (CHD) have been completed, and Synagis should be administered in a dose of 15 mg/kg intramuscularly using aseptic technique, preferably in the upper anterolateral aspect of the upper thigh.