

Important Safety Information

What is Synagis® (palivizumab)?

Synagis is a prescription medication that is used to help prevent a serious lung disease caused by respiratory syncytial virus (RSV) in infants and children at high risk for severe lung disease from RSV. Over one million children have been given Synagis. It is given as a shot, usually in the thigh muscle, each month during the RSV season. Children who develop an RSV infection while receiving Synagis should continue the monthly dosing schedule throughout the season.

Who should not receive Synagis?

Synagis should not be used in children who have ever had a severe allergic reaction to Synagis or its ingredients. Signs and symptoms of a severe allergic reaction could include: a drop in blood pressure; itchy rash; difficulty breathing; difficulty swallowing; swelling of the face; bluish color of the skin; muscle weakness or floppiness; and/or unresponsiveness. If your child has any of these signs or symptoms of a severe allergic reaction after getting Synagis, be sure to tell your child's healthcare provider or get medical help right away.

What are the side effects with Synagis?

Possible, serious side effects include severe allergic reaction which may occur after any dose of Synagis. Such reactions may be life-threatening or cause death. Unusual bruising and/or groups of tiny red spots on the skin have also been reported.

Common side effects of Synagis include fever, cold-like symptoms (upper respiratory tract infection), including runny nose and ear infection, and rash. Other possible side effects include skin reactions around the area where the shot was given (like redness, swelling, warmth or discomfort). In children born with certain heart problems, other possible side effects include bluish color of the skin and abnormal heart rhythms.

These are not all the possible side effects of Synagis. Tell your child's healthcare provider about any side effect that bothers your child or that does not go away.

Please see accompanying full product information, including information for patients and their caregivers at www.synagis.com and 1-877-633-4411.