

Respiratory Syncytial Virus (RSV) Prevention Synagis® (Palivizumab) Fact Sheet

Synagis® (Palivizumab) is a biologic medication that provides antibodies to protect children who are at high risk of becoming infected with respiratory syncytial virus. With vaccines, your child creates their own antibodies for long-lasting protection; however, when the antibodies are from a medication, they need up to five injections to keep them protected during the winter months.

What is respiratory syncytial virus?

- Respiratory syncytial virus (RSV) is a highly contagious viral infection, common in the winter.
- RSV is the most common respiratory illness in children under 5 years of age and infects nearly all children by their second birthday, with the highest rate among young infants.
- Most children and adults who develop an RSV infection have mild symptoms for one or two weeks of a “bad cold,” such as fever, nasal congestion / discharge, and a cough.
- However, high-risk infants, including premature infants or those with chronic lung or heart disease, are more likely to have severe breathing problems with an RSV infection, such as wheezing (bronchiolitis) and / or pneumonia.
- Premature babies tend to have smaller lungs and airways, so an RSV infection is worse for them; also, infants born at 32 to 35 weeks gestation have only half as many of the mother’s protective antibodies as full-term babies since they receive them mainly in the last trimester.
- RSV is the number one cause of hospitalization in children under one year of age.
- For high-risk infants, Palivizumab / Synagis® is available to prevent them from being infected with RSV, and it can reduce the rate of RSV hospitalizations by 78% for infants 35 weeks or less gestational age, and 80% for infants 32-35 weeks gestational age.

Who is eligible for RSV prophylaxis with Synagis®?

To be eligible for the RSV Program, the infant must

- meet the RSV Program’s listed clinical criteria, for example
 - all infants born under 33 weeks gestational age are accepted
 - preemies born under 36 weeks gestational age and **6 months of age or younger** at the beginning of RSV season are accepted
- be a resident of Ontario and insured under the Ontario Health Insurance Plan (OHIP)

Who should not receive Synagis?

Your infant should not receive Synagis® if they

- have an allergy to any of the components: palivizumab – (no preservatives); non-medicinal ingredients: chloride, glycine, histidine, mannitol, water for injection; vial stopper **does not contain latex**.
- have ever had a severe allergic reaction to Synagis® before, including
 - severe rash, hives, or itching skin
 - swelling of the lips, tongue, or face closing of the throat, difficulty swallowing, difficult, rapid, or irregular breathing
 - bluish color of skin, lips, or under fingernails (if unusual for your infant)
 - muscle weakness or floppiness, unresponsiveness (if unusual for your infant)

What are the common side effects of Synagis®?

- Some infants may be sore, red, or swollen where the needle was given.
- Some infants may develop a fever or a rash, feel achy or irritable, seem tired, or have the symptoms of a cold.
- Tylenol® / acetaminophen (or liquid ibuprofen if your infant is over 6 months of age), may be taken afterwards, as directed, to reduce discomfort or fever.
- **Children under 19 yrs of age must not be given ASA, Aspirin® or salicylates.**

What else do I need to know?

- RSV treatment usually starts in the third week of November and ends around April 1st.
- Synagis® does not protect against the flu, so unless there are medical reasons not to vaccinate against the flu, every child 6 months of age and older should get a flu shot, and two doses are recommended the first time, at least 4 weeks apart.
- It is recommended that Synagis® be given 24 hours before or after a routine vaccination / flu shot for proper monitoring of side effects, but if this is not possible due to the parent's schedule, the shots may be given on the same day; the research says it is okay.
- On very rare occasions, life-threatening anaphylactic reactions have occurred after Synagis® (less than 1 case per 100,000) and fatalities have been reported; however, the Hospital for Sick Children states "the risk of [Synagis®] causing serious harm is extremely small. Life-threatening allergic reactions are very rare. The most common side-effects are fever, irritability, or redness at the injection site."
- The benefits of up to an 80% reduction for preemies in the number of hospitalizations for RSV, after Synagis® preventative treatment, far outweigh the risks of the medication.
- Do not delay or miss a dose of Synagis®, if at all possible.
- Tell the nurse if your infant has any bruising or bleeding problems, since Synagis® is given by intramuscular injection.
- If your infant is taking a blood thinner, e.g. enoxapram, apply pressure to the site of the injection for at least 5 minutes afterwards.

When should I seek medical help after my infant receives an injection of Synagis®?

- If your infant experiences any unusual side effects, please seek medical attention and notify public health, as well.
- Call 911 or go to Emergency at a hospital right away if your infant has any of the following symptoms after receiving Synagis®:
 - swelling of the face and neck or problems breathing
 - hives and itchy, reddened skin
 - unusual bleeding at the injection site
 - unusual bruising or groups of tiny red spots on the skin

Other Questions?

Talk to your health care provider or call our Immunization Program at 613-966-5500 or 1-800-267-2803, ext. 221. | TTY Dial 711 (1-800-267-6511) | hpePublicHealth.ca

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