

Ministry of Health

Infant and High-risk Children Respiratory Syncytial Virus (RSV) Prevention Program – Monoclonal Antibody for Infants and High-risk Children

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This fact sheet provides basic information only. It is not intended to provide or replace medical advice, diagnosis, or treatment. You should talk to a health care professional about health concerns and illness.

Protecting Your Infant from RSV: Understanding Your Options

Two safe and effective ways to help prevent RSV infections in infants are available in Ontario: vaccination during pregnancy (Abrysvo™) and monoclonal antibodies (Beyfortus™) given after birth.

Generally, only one product is recommended to help protect an infant from RSV. Using both the vaccine and the monoclonal antibody is not necessary, unless the infant is high-risk (e.g., monoclonal antibody is recommended for all infants with certain medical conditions such as cardiac disease) per recommendation by a health care provider.

The National Advisory Committee on Immunization (NACI) recommends the monoclonal antibody product, Beyfortus™, be used over the vaccination of the pregnant individual based on its efficacy (i.e., how well it works), duration of protection, and safety profile.

This fact sheet presents information only for the monoclonal antibody prevention product Beyfortus™. For information about the vaccine available to pregnant persons, please see the *Infant RSV prevention program – Vaccine for pregnant individuals*.

Beyfortus™ Provides Immediate RSV Protection for Infants

Beyfortus™ is an injectable monoclonal antibody given to infants soon after birth during the RSV season, young infants born prior to the RSV season, and high-risk children during their second RSV season. The RSV season is generally from November to April,

peaking in December. Monoclonal antibodies provide immediate protection by supplying the body with ready-made antibodies, a process known as passive immunity. Beyfortus™ offers strong protection during the crucial early weeks and months when infants are most vulnerable to severe RSV disease.

For the 2024/25 RSV season, Beyfortus™ will be the publicly funded monoclonal antibody product for eligible infants. Per Health Canada's authorization, Beyfortus™ is designed to help prevent severe RSV disease in infants and young children. Beyfortus™ offers immediate protection and works best within the first six months after administration. Protection decreases over time and does not provide long-term immunity.

Eligibility for Beyfortus™ in the 2024/25 RSV Season

NACI recommends Beyfortus™ for any infant less than 8 months of age entering or born during their first RSV season. For the 2024/25 RSV season, the monoclonal antibody, Beyfortus™, is currently funded for RSV prevention in infants and children who are residents of Ontario and meet any of the following criteria:

- Born in 2024 prior to the RSV season
- Born during the 2024/25 RSV season
- High-risk children up to 24 months of age who remain vulnerable from severe RSV disease through their second RSV season, with:
 - Chronic lung disease of prematurity (CLD), including bronchopulmonary dysplasia/chronic lung disease
 - Hemodynamically significant congenital heart disease (CHD)
 - Severe immunodeficiency
 - Down syndrome/Trisomy 21
 - Cystic fibrosis with respiratory involvement and/or growth delay
 - Neuromuscular disease
 - Severe congenital airway anomalies impairing clearing of respiratory secretions

Please speak with a health care provider or local public health unit if you have questions regarding eligibility.

Beyfortus™ is Safe and Effective

Parents and caregivers are naturally concerned about the safety of any medication or treatment given to their baby. According to NACI and the regulator Health Canada, Beyfortus™ is safe for most infants.

When given to infants entering their first RSV season, Beyfortus™ does not increase the risk of severe side effects compared to a placebo. Clinical trials have shown that Beyfortus™ is safe for most full-term and preterm infants (born at least 29 weeks

gestation). The rates of side effects were similar between infants receiving Beyfortus™ and those receiving a placebo (84.0% vs. 82.6%).

Beyfortus™ is very effective in preventing RSV-related illnesses in infants. Beyfortus™ was used in many locations worldwide during the 2023/24 RSV season, including the US, France, and Spain. The real-world results from monitoring those programs were similar to those seen in clinical trials:

- Prevention of 82% - 90% of RSV-associated lower respiratory tract infection (LRTI) requiring hospitalization
- Prevention of 75.9% - 90.1% of RSV-associated Intensive Care Unit admissions
- 69% - 90% overall reduction in RSV-associated hospitalizations compared to the previous season

Possible Side Effects of Beyfortus™

RSV prevention products, whether the monoclonal antibody or vaccine, may have some side effects. These are usually mild and last only a few days. Common side effects after Beyfortus™ include local reactions at the injection site, such as redness, swelling, and pain. Other mild side effects observed are rash and fever. Receiving Beyfortus™ will not give an infant RSV, as it is an antibody and not the virus that is in the product.

It is essential to discuss the benefits and risks of RSV monoclonal antibodies with a health care provider and report any adverse events to them. If severe reactions develop, including hives, swelling of the mouth or throat, trouble breathing, hoarseness or wheezing, high fever (over 40°C or 104°F), seizures, or other severe reactions, go to the nearest emergency department.

Administering Beyfortus™ with Other Pediatric Vaccines

Beyfortus™ may be given on the same day as other recommended pediatric immunizations listed in the [Ontario Publicly Funded Immunization Schedule](#). Studies have shown that giving Beyfortus™ and other vaccines on the same day or within a week before or after has similar safety and side effects as giving the vaccines separately.

Administering Beyfortus™ During Illness

If your baby has a severe acute illness, with or without fever, symptoms should disappear before receiving Beyfortus™. A minor illness, such as a cold, should not result in the deferral of administration. Please speak to a health care provider if your baby is unwell before receiving the injection.

Use of Beyfortus™ After a Previous RSV Infection

Beyfortus™ is usually unnecessary for an infant with an RSV infection during the current season. The extra benefit of giving Beyfortus™ in the same season after an infant has recovered from RSV is not clear and is likely to be small because the chance of getting seriously sick from RSV again in the same season is very low.

However, an infant with a weakened immune system might still benefit from Beyfortus™ because their body may not fight the RSV infection. If your infant has a medical condition that weakens their immune system, discuss Beyfortus™ use after an RSV infection with a health care provider.

Additional Information

For more information about RSV, RSV prevention products, or the province's RSV prevention program, please refer to the ministry's [RSV website](#) or contact your local public health unit. You may also contact a primary health care provider.