Ontario

Ministry of Health

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

Version 1.0 – August 8, 2024

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.

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Infant and High-risk Children Respiratory Syncytial Virus (RSV) Prevention Program - Vaccine for Pregnant Individuals

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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 of these products 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®, 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 about the Abrysvo™ vaccine for pregnant individuals. For information about the antibody prevention product available to infants, please see the fact sheet, *Infant RSV prevention program – Monoclonal antibody for infants and high-risk children.*

Vaccination for Pregnant Individuals

Health Canada authorized the Abrysvo™ vaccine to be given to pregnant individuals between 32 and 36 weeks of pregnancy if they will deliver near the start of or during RSV season. The RSV season is generally from November to April, peaking in December. In response to the vaccine the pregnant person creates antibodies that are

passed to the infant to protect them from RSV from birth until approximately six months old. Abrysvo™ helps provide immediate protection against severe RSV infections right from birth.

Eligibility for Abrysvo™ in the 2024/25 RSV Season

Individuals must be Ontario residents to be eligible for the publicly funded program.

For the 2024/25 RSV season, Abrysvo™ is available for pregnant individuals from 32 to 36 weeks gestational age, in consultation with their health care provider, as the monocloncal antibody, Beyfortus®, is the recommended product over vaccination to help protect infants per NACI.

Safety and Effectiveness of Abrysvo™ for Pregnant Individuals

According to NACI, Abrysvo™ is safe for most pregnant individuals when administered later in pregnancy, as Health Canada has approved.

Clinical trial data shows that Abrysvo™ is safe and effective for most pregnant individuals to help prevent severe RSV disease in their babies from birth up to 6 months old. Over 7,000 pregnant participants received either the RSV vaccine or a placebo in the trials. The vaccine reduced the chances of hospitalization for RSV by 68% within the first three months after birth and by 57% within six months. It also lowered the risk of severe RSV disease in the infant by 82% within three months and 69% within six months after birth.

The following should specifically be discussed with a health care provider before Abrysvo™ is received:

- Allergy to any of the ingredients;
- severe allergic reaction or breathing problems after other vaccines;
- bleeding problem or bruise easily;
- infection with a high fever;
- weakend immune system; or
- are less than 32 weeks pregnant.

Possible Side Effects of Abrysvo™

Like any vaccine or medicine, RSV prevention products may have side effects. Per the clinical trials and use of the products in other countries, the side effects are typically mild and usually last only a few days. Common side effects after the Abrysvo™ vaccine reported during clinical trials included pain at the injection site, headache, muscle aches, and nausea.

In clinical trials, the RSV vaccine group had slightly more preterm births than the placebo group, but the difference wasn't statistically significant. This means current data cannot confirm whether the vaccine directly causes preterm birth..Consequently, at this time, limiting vaccine administration to the Health Canada approved dosing interval of 32 to 36 weeks gestation reduces the potential risk of preterm birth.

It is essential to discuss the benefits and risks of the RSV vaccine 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 serious reactions, go to the nearest emergency department.

Administering Abrysvo™ with Other Vaccines

Abrysvo™ may be given on the same day as tetanus, diphtheria, acellular pertussis, COVID-19, and influenza vaccines. If another immunization must be given at the same visit, they should be administered in different limbs to reduce any risk of increasing pain or other local reactions.

Administering Abrysvo™ During Illness

Whether you should receive Abrysvo™ during illness depends on the severity of symptoms. If you have a severe acute illness, with or without fever, you should wait until symptoms disappear before receiving Abrysvo™. A minor illness, such as a cold should not result in the deferral of administration. Please speak to a health care provider if you are unwell before receiving the injection.

Receiving Abrysvo™ After a Previous RSV Infection

Immunization with Abrysvo™ may be administered regardless of past RSV infection. No specific interval is recommended between RSV infection and RSV vaccination. However, if you have severe illness, immunization should be deferred until you feel better.

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.