

Ministry of Health

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

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 (AbrysvoTM) 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 AbrysvoTM 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. AbrysvoTM 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 AbrysvoTM 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 AbrysvoTM 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 AbrysvoTM 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 AbrysvoTM. 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 AbrysvoTM 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 <u>RSV website</u> or contact your local public health unit. You may also contact a primary health care provider.