Respiratory Syncytial Virus Vaccines for Providers

Fall/Winter 2024

Antoinette Yuhas, Public Health Nurse Specialist

Immunization Program

Ohio Department of Health

Department of Health

Objectives

After viewing the Respiratory Syncytial Virus (RSV) presentation, vaccine providers should:

- Be aware of the available RSV vaccines.
- Know the age-appropriate use for each RSV product.
- Know the unique storage and handling considerations for each RSV vaccine.
- Know the RSV vaccination administration guidelines for each vaccine.
- Be aware of available RSV resources.

Ohio Department of Health

Purpose

There are several vaccines available to help prevent and lessen the effects from **Respiratory Syncytial Virus (RSV)**.

These vaccines are created to protect populations with the highest risks for lower respiratory tract infections: **the very young and the elderly**.

Currently, only **one dose** of an RSV vaccine is needed to provide protection for **adults**.

Infants without immunocompromising conditions also only receive **one dose**.

Image of people ages 75 years.
Image of newborns.

Ohio Department of Health

RSV Vaccines For Adults

The Centers for Disease Control and Prevention (CDC) recommends RSV vaccination for **all adults ages 75 years and older** and for **adults ages 60-74 years who are at increased risk of severe RSV disease**.

Ohio Department of Health

CDC RSV recommendations for adults.

RSV Vaccines For Adults

There are three RSV vaccines approved for **adults ages 60 years and older or for maternal vaccination**:

- **Pfizer's ABRYSVO.**
  - Protein subunit RSV vaccine.
  - Only adult vaccine recommended as a maternal vaccination to protect newborn infants.
- **GSK's AREXVY.**
  - Protein subunit RSV vaccine, adjuvanted.
- **Moderna's mRESVIA.**
  - mRNA RSV vaccine.

Ohio Department of Health

CDC RSV recommendations for adults.

RSV Vaccines For Adults

Eligible adults can get an RSV vaccine at any time, but the best time to get vaccinated is in **late summer** and **early fall** before RSV usually starts to spread in the community.

Ohio Department of Health

CDC RSV recommendations for adults.

RSV Vaccines For Adults

All three of these vaccines cause the immune system to produce RSV antibodies and are currently approved as **a single dose** to protect against RSV in adults **ages 60 and older.**

Based on clinical trial data, one dose of RSV vaccine can provide protection for **at least two years.**

Ohio Department of Health

CDC RSV recommendations for adults.

RSV Vaccines For Adults

- CDC and ODH do not have a preferential recommendation for any specific vaccine.
- Eligible adults should receive whichever vaccine is available.

Ohio Department of Health

Abrysvo carton. Arexvy carton. mRESVIA carton. CDC RSV recommendations for adults.

RSV Vaccine or Monoclonal Antibody For Infants

RSV usually causes mild symptoms but can cause severe illness in infants and some young children.

There are two safe and effective immunizations to prevent lower respiratory tract infection in infants.

- A **maternal vaccination** (Pfizer's **ABRYSVO**) given to the mom during pregnancy.
- A **monoclonal antibody (Beyfortus)** given to the **baby** shortly after birth.

Either one is recommended, but administration of both, the maternal and the monoclonal, is not needed to protect most infants.

Ohio Department of Health

RSV Vaccine For Infants

The packaging for ABRYSVO and for Beyfortus is different and should help health care staff avoid confusion when using the correct product.

Maternal vaccination: Abrysvo

Monoclonal antibody: Beyfortus

Ohio Department of Health

Abrysvo carton. Beyfortus 100mg. Beyfortus 50mg.

Maternal Vaccination (ABRYSVO)

Ohio Department of Health

ABRYSVO: Infant Protection Through Maternal Vaccination

Pfizer's ABRYSVO is **the only RSV vaccine approved for maternal vaccination** to prevent RSV in infants.

- ABRYSVO for maternal vaccination is administered to pregnant women in their **gestational weeks 32 through 36 and six days**.
- **Do not** administer **after the 37th gestational week**.
- Infants born to mothers who received ABRYSVO will **most likely not** require Beyfortus vaccination at birth.

Pregnant woman image.

Ohio Department of Health

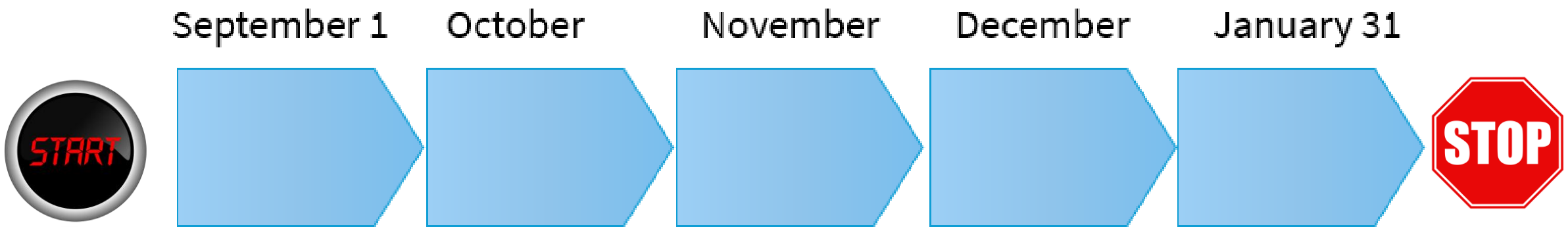
Maternal Vaccination

Pregnant women are at a higher risk of developing lower respiratory tract issues from RSV infection. In most parts of the U.S., **RSV circulation is seasonal**, typically starting during the fall and peaking in the winter.

In Ohio, pregnant women gestational weeks 32 – 36 and six days can be vaccinated with ABRYSVO:

Beginning: **September first** (1st).

Ending: **last day of January** (31st) the following year.



Ohio Department of Health

Maternal Vaccination

Infants born to mothers who received ABRYSVO will **most likely not** require Beyfortus vaccination at birth.

ABRYSVO may be received during one pregnancy only.

- If the mother received ABRYSVO during pregnancy and gave birth, then becomes pregnant again, the **following child or children will receive Beyfortus**.

All RSV vaccinations for adults are one-time (one dose) only.

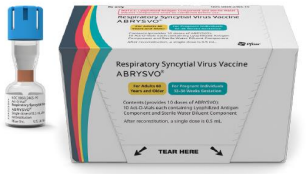
Ohio Department of Health

Image of pregnant woman.

ABRYSVO Administration

There are three presentations of ABRYSVO available for intramuscular injection (0.5mL).

1. ABRYSVO Act-O-Vial is supplied in cartons of one (1) and 10 Act-O-Vials, without syringes or needles. This is a double chambered vial with a stopper separating the lyophilized antigen from the sterile water diluent. A syringe with needle is required for administration. Note: this product is not available through VFC in Ohio.
2. ABRYSVO vial and prefilled syringe presentation is supplied in cartons of one (1), five (5), and 10 kits, without needles. Each kit includes a vial of Lyophilized Antigen Component, a prefilled syringe containing Sterile Water Diluent Component, and a vial adapter. **Note: this product is available through VFC in the one (1) kit presentation in Ohio.**
3. ABRYSVO vial and vial presentation is supplied in cartons of five (5) and 10 doses packaged without syringes or needles. Each carton includes vials of Lyophilized Antigen Component and vials of Sterile Water Diluent Component. Note: this product is not available through VFC in Ohio.



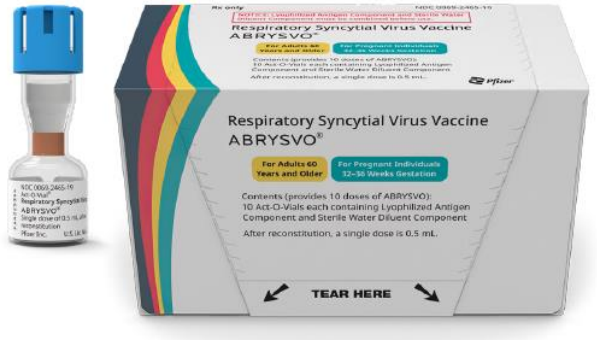
Please see ABRYSVO's package insert for specific instructions on reconstituting the vaccine for each type of presentation .

Ohio Department of Health

ABRYSVO Administration

Act-O-Vial:

- This is a double chambered vial with a stopper separating the lyophilized antigen from the sterile water diluent.
- A syringe with needle is required for administration.
- Dose volume is 0.5mL.
- Discard excess reconstituted vaccine.



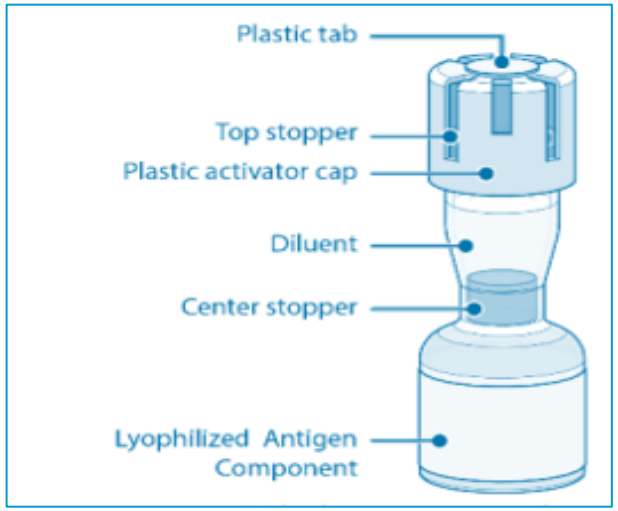
Please see Abrysvo's package insert for specific instructions on reconstituting the vaccine for each type of presentation .

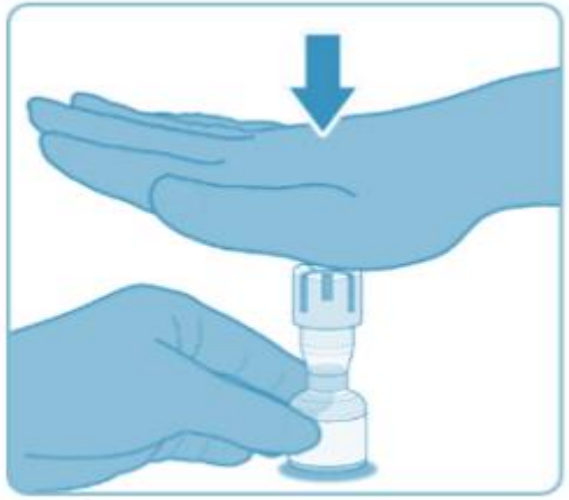
Ohio Department of Health

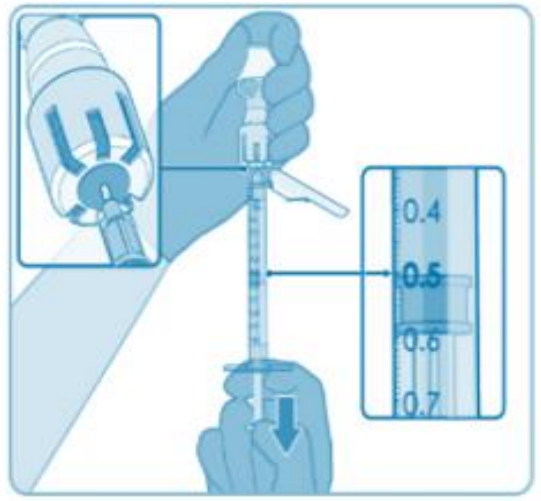
ABRYSVO Presentation

Abrysvo "Act-O-Vial" Presentation.

- The Act-O-Vial presentation is supplied in cartons.
- Each Act-O-Vial contains the Lyophilized Antigen Component (a sterile white powder) and Sterile Water Diluent Component.
- Requires needle and syringe for administration (not included).







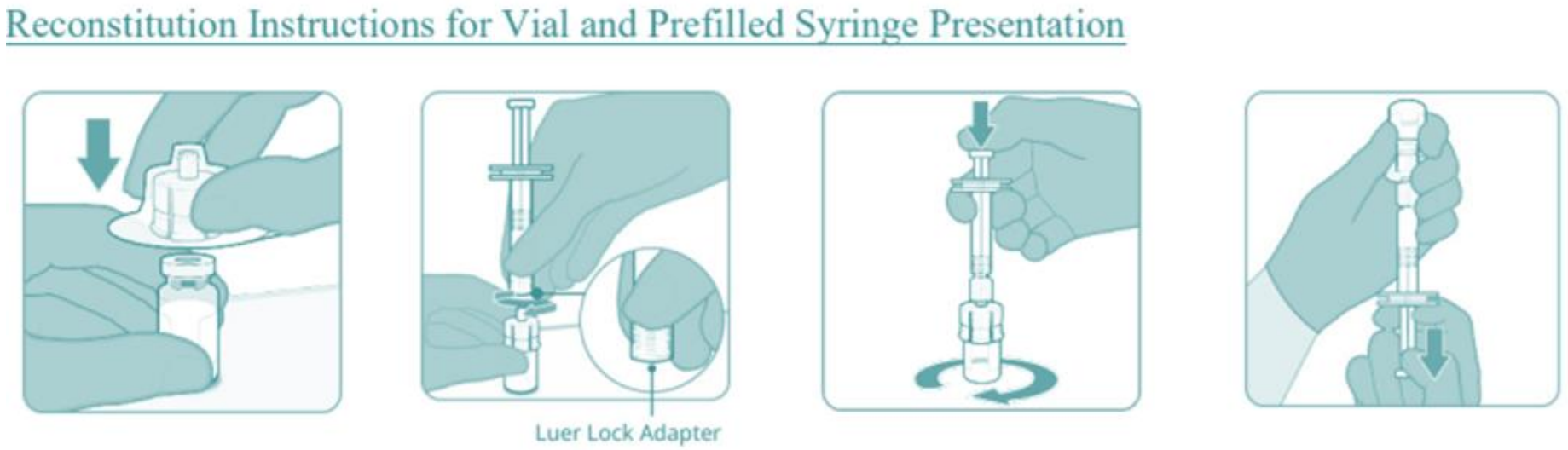
Ohio Department of Health

Presentation reconstituting infographics.

ABRYSVO Presentation

Vial and Prefilled Syringe Presentation.

- The vial and prefilled syringe presentation is supplied in cartons containing a kit(s).
- Each kit includes a vial of Lyophilized Antigen Component (a sterile white powder), a prefilled syringe containing Sterile Water Diluent Component, and a vial adapter.



Department of Health

Presentation reconstituting infographics.

ABRYSVO Storage and Handling

Before reconstitution:

- Store vaccine **and** diluent refrigerated between 2°C and 8°C (36°F and 46°F).
- Store these components in their original package and keep them together in the refrigerator to optimize organization.
- **<u>Never freeze</u> the vaccine or diluent.**

Image of vaccine refrigerators.

Ohio Department of Health

ABRYSVO Storage and Handling

After reconstitution:

- Immediately administer the vaccine; you should prepare the vaccine only when ready for use.

- If you **do not immediately administer** the vaccine, there are some minor differences in storage:
  - **Store the reconstituted vaccine ONLY at room temperature** [15^{0}C to 30^{0}C or (59^{0}F to 86^{0}F)] and use within four hours.
  - **Do NOT refrigerate.**
  - This is very different than other reconstituted vaccines. For this vaccine, **DO NOT put it back in the refrigerator after reconstitution.**
  - **Never freeze** the vaccine or diluent.

Ohio Department of Health

ABRYSVO Storage and Handling

Once you've reconstituted the vaccine, you **begin a four-hour beyond-use date clock**.

You must use the reconstituted vaccine **within four hours**.

- When the **four hours have passed,** the dose must be **wasted and disposed**.
- Do not administer expired vaccine.

Four-hour clock window.

Ohio Department of Health

Monoclonal Antibody For Infants (Beyfortus)

Ohio Department of Health

RSV Prevention For Infants

- RSV is the most common cause of hospitalization in infants.
- RSV can cause serious illness and death in infants and young children.
- Severe RSV lower respiratory tract infection **in infants** can be prevented by administering either:
  - **Monoclonal antibody** products to **infants and young children**, or
  - **ABRYSVO** to the **mother during pregnancy**.

Ohio Department of Health

Monoclonal Antibody Products For Infants

There are two injectable monoclonal antibody products that help protect infants and young children from lower respiratory tract infection caused by RSV.

- Nirsevimab (Beyfortus).
- Palivizumab (Synagis).

This presentation will focus on Beyfortus.

Ohio Department of Health

Beyfortus

- Beyfortus is an injectable monoclonal antibody that prevents severe RSV disease in infants and young children.

- Monoclonal antibodies do not activate the immune system, as would occur with infection or vaccination (active immunization).

- Rather, the antibodies themselves protect against disease (passive immunization).

Ohio Department of Health

Beyfortus

- Beyfortus does not activate the immune system, so protection is likely most effective for several weeks after administration, and wanes over time.

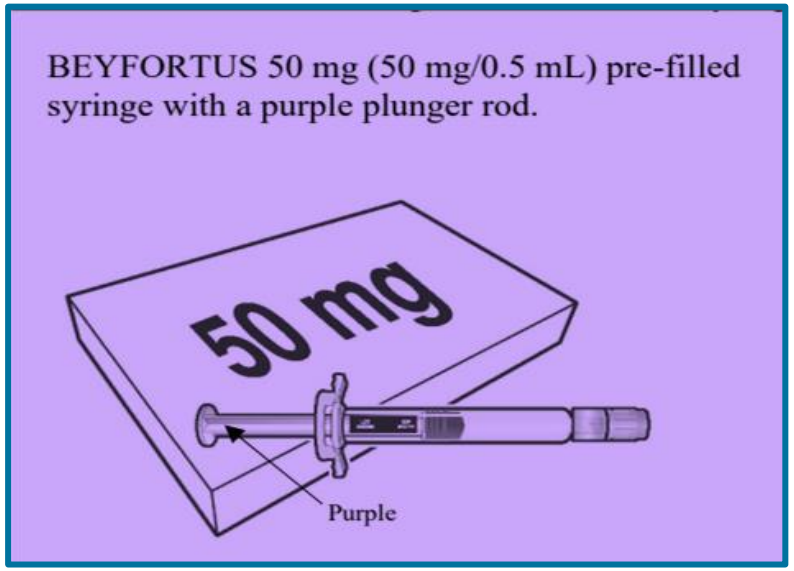
- Beyfortus does not provide long-term immunity to RSV disease but provides protection to infants when they are most at risk of getting severe RSV disease.

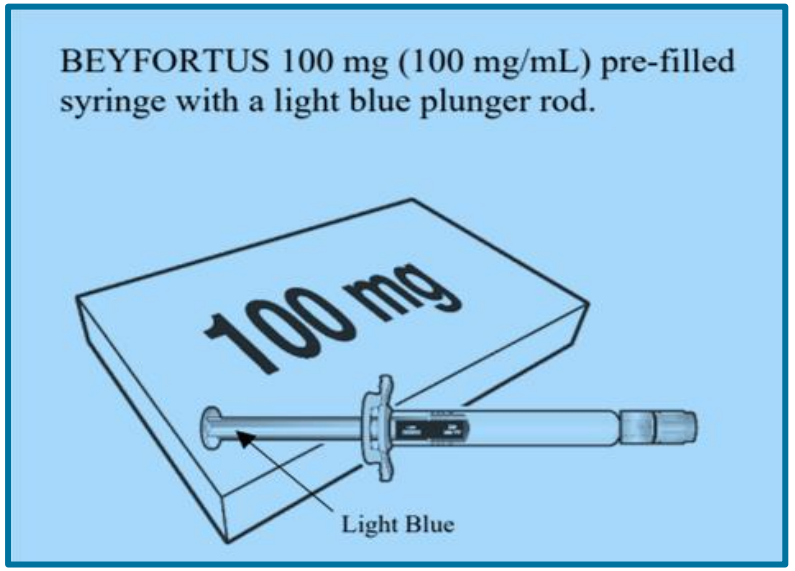
- As children get older, they are less likely to get severe symptoms from RSV infection.

Ohio Department of Health

Beyfortus

- Beyfortus is available in a 50 mg (0.5mL) and a 100 mg (1.0mL) single use, pre-filled syringe.
- Check the labels on the carton and pre-filled syringe to ensure the correct dosage of product is being used.





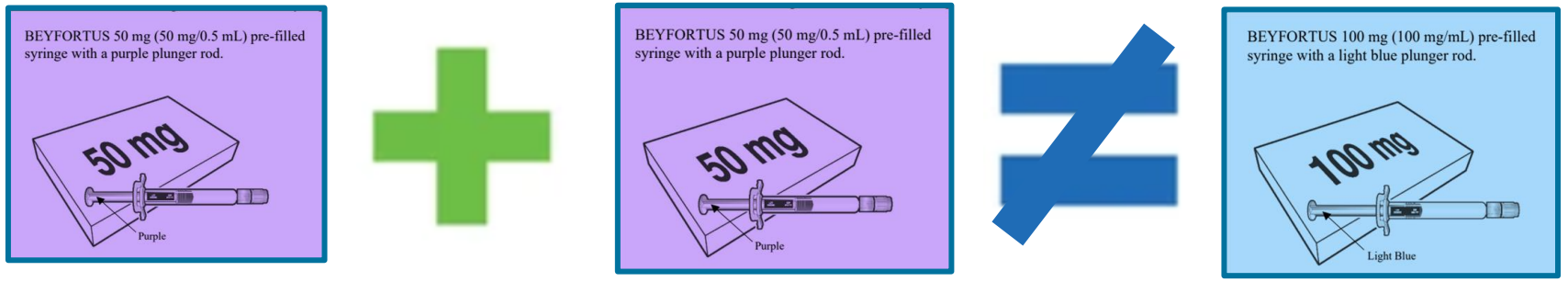
Ohio Department of Health

Beyfortus

The correct dose by weight must be used.

- You **cannot use** two 50mg doses if a 100mg dose is required.
- You **cannot use** half of a 100mg dose if 50mg dose is required.

DON'T



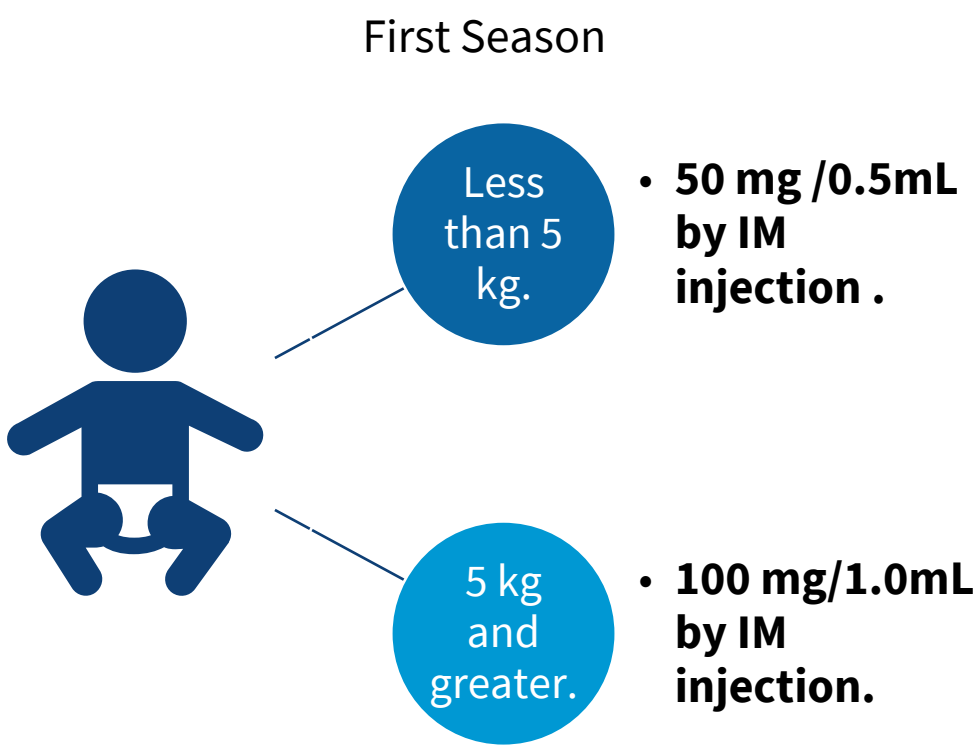
DON'T

Ohio Department of Health

Math symbols.
Dos and Don'ts.
Division symbol.

Beyfortus

- Beyfortus is given during the infant's **first RSV Season** before they are eight months old.
- The dose is based upon their weight.
  - If the infant is **less than 5 kilograms**, they receive a **50mg/0.5mL/IM**.
  - If they weigh **5 kilograms or more**, they will receive **100mg/1.0mL/IM**.



Ohio Department of Health

RSV First Season - One Dose For Infants

One dose of Beyfortus is recommended for infants younger than eight months of age who were born shortly before or are entering their first RSV season (typically fall through spring) if:

- The mother did not receive an ABRYSVO vaccination during pregnancy.
- The mother's RSV vaccination status is unknown.
- The infant was born within 14 days of maternal RSV vaccination.

Ohio Department of Health

RSV First Season - One Dose For Infants

- Except in rare circumstances, Beyfortus is not needed for most infants younger than age eight months who are born 14 or more days after their mother received an ABRYSVO vaccination.

Ohio Department of Health

RSV Season Two - For Older Infants

- Beyfortus is recommended for some children aged **eight through 19 months** old **who are at increased risk** for severe RSV disease and entering their second RSV season.

- These infants are recommended to receive Beyfortus shortly before or during their second RSV season.

Ohio Department of Health

RSV Season Two - For Older Infants

Older infants at increased risk include:

- American Indian/Alaska Native children.
- Children with chronic lung disease of prematurity who require medical support during the six months before the start of their second RSV season.
- Children with severe immunocompromise.
- Children with severe cystic fibrosis.

Children ages eight months and older **who are not at increased risk** of severe RSV disease **should not receive** Beyfortus for their second season.

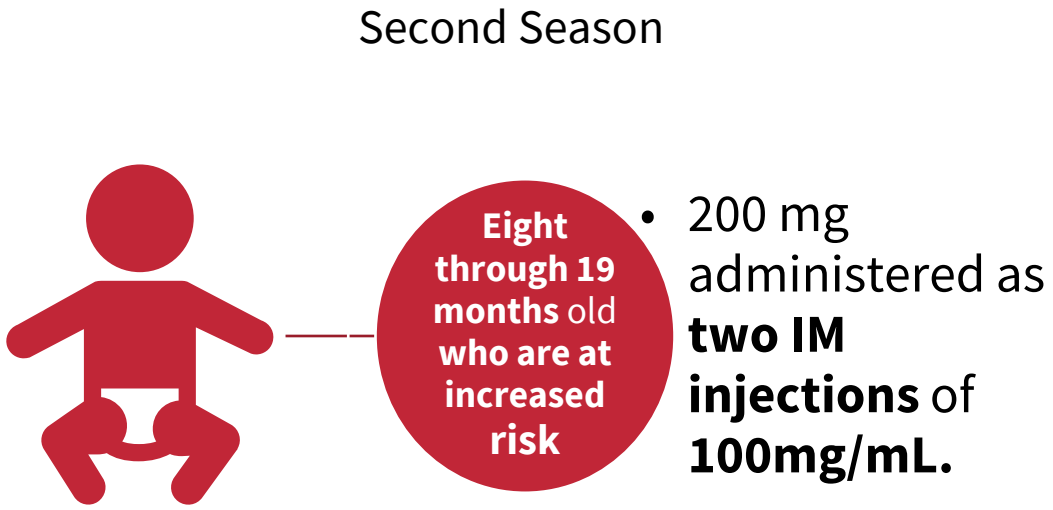
Ohio Department of Health

RSV Season Two - For Older Infants

- For **RSV Season Two** infants and young children eight months through 19 months of age, will receive a total dose of **200mg**.

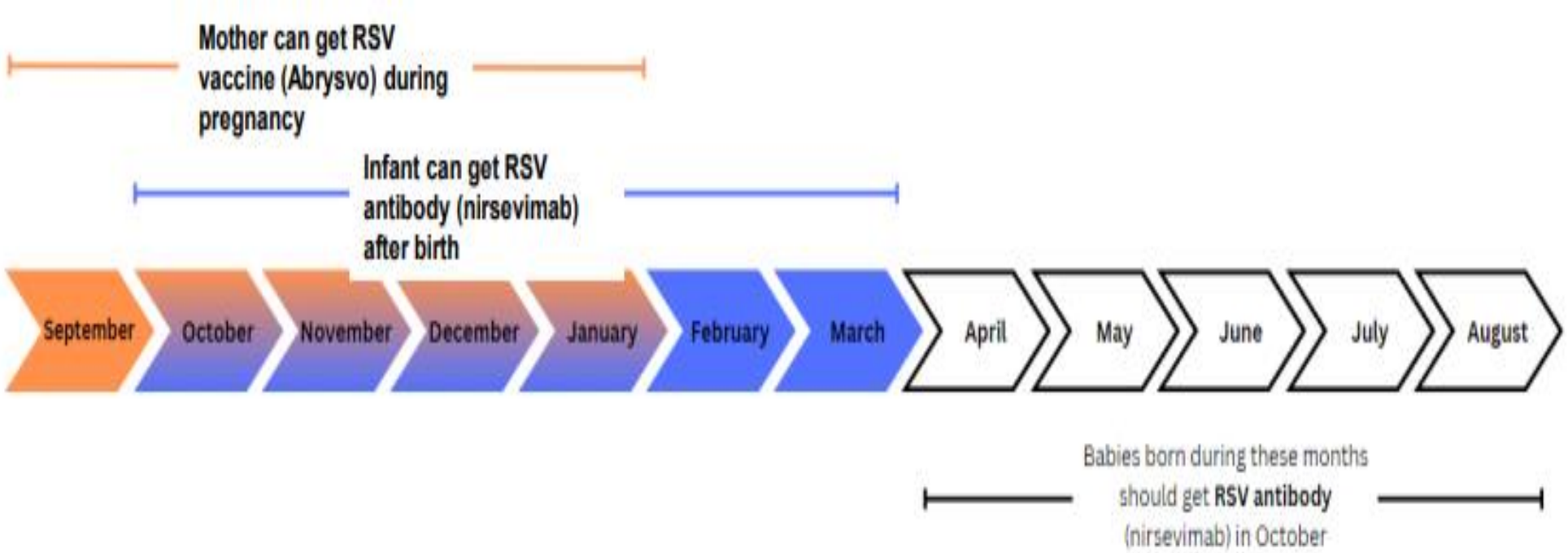
- That is achieved by giving **<u>two</u>, 100mg/1.0mL** doses (one dose in each leg).

- Regardless of body weight.



Ohio Department of Health

Timing of Abrysvo and Beyfortus Administration



Department of Health

NFID Slide for Abrysvo and Beyfortus timing.

Adult Vaccine (AREXVY)

Ohio Department of Health

AREXVY

- AREXVY is for adults ages 60 years and older.
- **DO NOT** give during pregnancy.
- **DO NOT** give to infants.

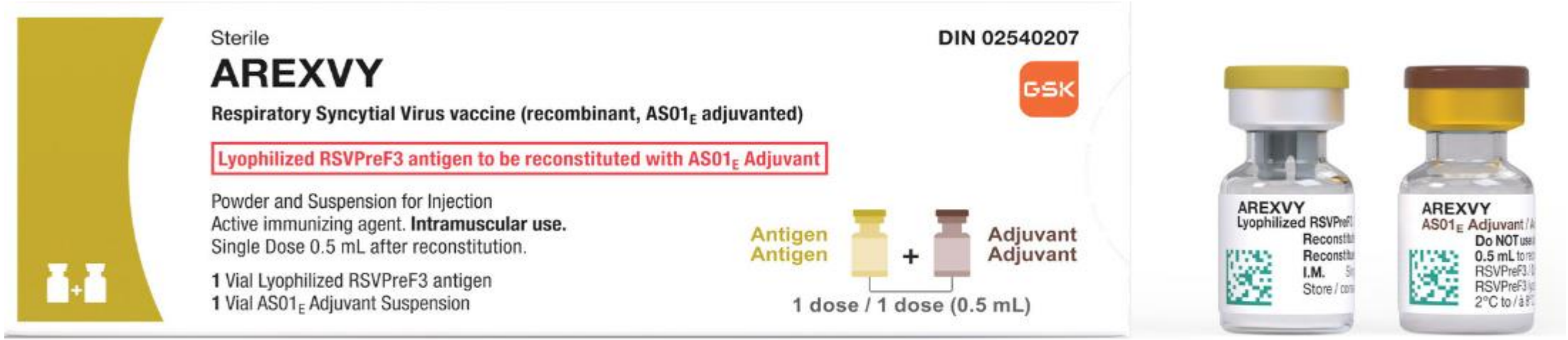
Arexvy carton image.

Ohio Department of Health

AREXVY

AREXVY is supplied in two vials that must be reconstituted prior to administration.

- One vial is a lyophilized antigen component and the second is a liquid diluent adjuvant suspension.
- You **MUST** use the diluent provided by the manufacturer.
- Refer to AREXVY's package insert for specific instructions on reconstituting the vaccine.



Arexvy carton and vials.

Ohio Department of Health

Storage and Handling

- Store AREXVY adjuvant suspension component **and** lyophilized antigen vials refrigerated between 2°C and 8°C (36°F and 46°F).

- Store in the original package to protect vials from light.

- **Do not freeze**.
  - Discard if the adjuvant suspension component and/or the lyophilized antigen component vials have been frozen.

Image of vaccine refrigerators.

Ohio Department of Health

AREXVY

Before reconstitution:

- Store vaccine **and** diluent refrigerated between 2°C and 8°C (36°F and 46°F).
- Store the vaccine and diluent in their original package and keep them together in the refrigerator to optimize organization.
- Never freeze the vaccine or diluent.
- Protect the vial from light.

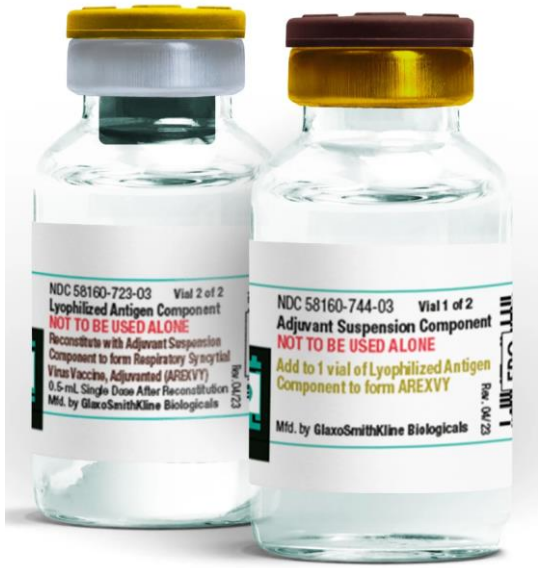


Image of Arexvy vials.

Ohio Department of Health

AREXVY

After reconstitution:

- Immediately administer the vaccine; you should prepare the vaccine only when ready for use.

- If you do not immediately administer the vaccine, there are some minor differences in storage:
  - Store the reconstituted vaccine refrigerated between 2°C and 8°C (36°F and 46°F) **OR at room temperature** [up to 25°C (77°F)]. Note: The difference is due to the allowance of storage at room temperature.
  - Never freeze the reconstituted vaccine.
  - Protect it from light.

AREXVY

- Once you've reconstituted the vaccine, you begin a **four-hour beyond-use date clock**.
- Reconstituted vaccine **must used within four hours.**
- When **past** the **four hours,** the reconstituted vaccine must be wasted and disposed.
- Do not administer expired vaccine.

Four-hour clock window.

Ohio Department of Health

Adult Vaccine (mRESVIA)

Ohio Department of Health

mRESVIA

- mRESVIA is a mRNA vaccine.
- For adults ages 60 years and older.
- **DO NOT** give during pregnancy.
- **DO NOT** give to infants.

Ohio Department of Health

mRESVIA

- Supplied in cartons of one or 10, prefilled plastic syringes (PFS).
- Syringes are in a blister pack.
- The 10-pack carton has two syringes in a five-blister pack.
- The dosage is only ONE 0.5mL PFS.

mRESVIA carton.

Ohio Department of Health

mRESVIA

- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Store **frozen** between -40°C to -15°C (-40°F to 5°F) until expiry.
- Refer to mRESVIA’ s package insert for specific instructions on storage and thawing.

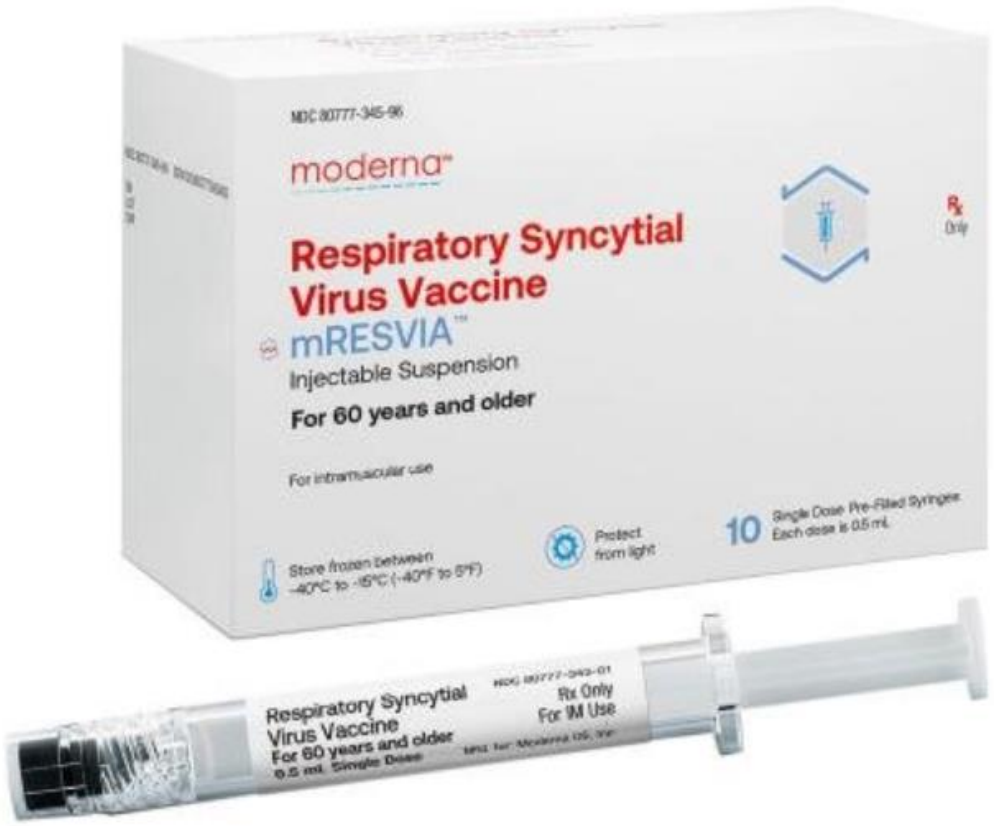
Vaccine Freezer image.

Ohio Department of Health

mRESVIA

Storage after Thawing:

- Storage at 2°C to 8°C (36°F to 46°F).
- Prefilled plastic syringes may be stored refrigerated between 2°C to 8°C (36°F to 46°F) **for up to 30 days prior to use.**



mRESVIA carton.

Ohio Department of Health

mRESVIA

- Pre-filled plastic syringes may be stored between 8°C to 25°C (46°F to 77°F) for a **total of 24 hours** after removal from refrigerated conditions. Total storage at 8°C to 25°C (46°F to 77°F) **must not exceed 24 hours**.
- Discard the prefilled syringe if not used within this time.
- **Should not be returned to the refrigerator after being thawed at room temperature.**
- Do not refreeze once thawed.
- Do not shake.

Ohio Department of Health

Vaccine Adverse Event Reporting System (VAERS)

Ohio Department of Health

VAERS

- National program managed by the CDC and the U.S. Food and Drug Administration (FDA) to monitor the safety of all vaccines licensed in the United States.
- Collects and reviews reports of adverse events that occur after vaccination.
- Early-warning system that detects problems possibly related to vaccines.

Ohio Department of Health

VAERS

Health professionals are tasked to report adverse events following any vaccination including but not limited to:

- Anaphylaxis or anaphylactic shock (three days).
- Shoulder Injury Related to Vaccine Administration (two days).
- Vasovagal syncope (one hour).
- Guillain-Barre Syndrome (three – 42 days).
- Any acute complication or sequelae (including death) of above events (interval - not applicable).
- Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert).

Ohio Department of Health

VAERS

VAERS reporting is easy and there are two options:

- Online, secure reporting.
- Writeable PDF Form.

If you need further assistance with reporting to VAERS, please email info@VAERS.org or call 1-800-822-7967.

Option 1 - Report Online to VAERS

Submit a VAERS report online. The report must be completed online and submitted in one sitting and cannot be saved and returned to at a later time. Your information will be erased if you are inactive for 20 minutes; you will receive a warning after 15 minutes.

Option 2 - Report using a Writable PDF Form

Download the Writable PDF Form to a computer. Complete the VAERS report offline if you do not have time to complete it all at once. Return to this page to upload the completed Writable PDF form by clicking here.

Ohio Department of Health

Resources

- **ABRYSVO.**
  - Pfizer’s ABRYSVO for Professionals.
  - ABRYSVO package insert.
  - Healthcare Providers: RSV Vaccination for Pregnant People | CDC.
- **AREXVY.**
  - AREXVY package insert.
- **mRESVIA.**
  - mRESVIA package insert.
- **Beyfortus.**
  - Nirsevimab Immunization Information Statement (CDC).

Ohio Department of Health

Resources

American Academy of Pediatrics.

- Nirsevimab Administration Visual Guide (AAP.org).
- Nirsevimab Frequently Asked Questions (AAP.org).
- Respiratory Syncytial Virus (Red Book).
- Palivizumab Prophylaxis in Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection (AAP Technical Report).
- Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection (AAP Policy Statement).

Ohio Department of Health

Resources

CDC/Health and Human Services (HHS) Resources.

- CDC MMWR Report on RSV Vaccines.
- CDC RSV Recommendations.
- CDC publication about RSV.
- Immunize.org Storage and Handling.
- VAERS Reportable Events Table.
- VAERS Reporting for Professionals.

Ohio Department of Health.

- Telephone: (614)466-4643.
  (Ohio only): 1-800-282-0546.
- Email: Immunize@odh.ohio.gov.

Ohio Department of Health

Resources

Immunization Program
Ohio Department of Health
246 North High Street
Columbus, Ohio 43215

Telephone: (614) 466-4643
1-800-282-0546 (Ohio only)
Fax: (614) 728-4279
Email: Immunize@odh.ohio.gov

Ohio Department of Health

QUESTIONS?

Ohio Department of Health

Department of Health