FOR INTRAMUSCULAR INJECTION



ABRYSVO[™] Needle-free* Reconstitution Kit Just CLICK, MIX, PREP to get started

*Needle required for intramuscular injection is not included.

ABRYSVO™ (Respiratory Syncytial Virus Vaccine) solution for intramuscular injection

INDICATION

ABRYSVO is a vaccine indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older.

IMPORTANT SAFETY INFORMATION

- Do not administer ABRYSVO to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of ABRYSVO
- · Appropriate medical treatment must be available in case of an anaphylactic reaction
- Syncope (fainting) may occur in association with administration of injectable vaccines, including ABRYSVO. Procedures should be in place to avoid injury from fainting
- Immunocompromised individuals, including those receiving immunosuppressive therapy, may have a diminished immune response to ABRYSVO
- · Vaccination with ABRYSVO may not protect all vaccine recipients
- In clinical trials, the most commonly reported (≥10%) adverse reactions were fatigue (15.5%), headache (12.8%), pain at the injection site (10.5%), and muscle pain (10.1%)

Patients should always ask their healthcare providers for medical advice about adverse events. You are encouraged to report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit <u>http://www.vaers.hhs.gov</u> or call 1-800-822-7967.

Please see full Prescribing Information for ABRYSVO.

ABRYSVO™ Preparation for Administration

Below are instructions for how to reconstitute the lyophilized antigen component with the prefilled syringe of sterile water diluent provided to prepare ABRYSVO.





Storage and Handling

Storage after reconstitution: ABRYSVO should be administered immediately or stored at room temperature [15°C to 30°C (59°F to 86°F)] and used within 4 hours. Do not store reconstituted vaccine under refrigerated conditions [2°C to 8°C (36°F to 46°F)]. Do not freeze reconstituted vaccine.

CLICK



- STEP 1. Open and attach vial adapter
- Open the vial adapter packaging by peeling off the top cover, but do not remove the adapter

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- Align the adapter spike over the center of the vial's rubber stopper
- Connect the vial adapter to the vial with a straight downward push, locking it into place. Do not push at an angle

STEP 2. Remove cap and connect syringe

- Remove the syringe cap while holding the Luer lock adapter
- Continue holding the syringe by the Luer lock and connect it to the vial adapter by turning clockwise. **Do not** overtighten



STEP 3. Inject diluent and gently swirl

MIX

 Inject the entire contents of the syringe containing the sterile water diluent into the vial. Do not remove the empty syringe

• While holding the plunger rod down, gently swirl the vial until the powder is completely dissolved. Do not shake

Scan the code or visit ABRYSVOPrep.com to watch a video on how to prepare ABRYSVO

PREP

STEP 4. Withdraw the contents

· Slowly withdraw the entire contents of the vial into the syringe to ensure an approximately 0.5 mL dose for administration

STEP 5. Disconnect syringe and attach needle



- Disconnect the syringe from the vial by holding the Luer lock adapter and turning counter-clockwise
- Attach a sterile needle suitable for intramuscular injection to the syringe
- Inspect prepared vaccine for particulate matter or discoloration prior to administration. Do not use if either is present

Please see Important Safety Information on previous page and full Prescribing Information.

