HEALTHCARE PROFESSIONAL POCKET GUIDE

RSV STOPS HERE

AREXVY is indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in individuals 60 years of age and older.[1]

Learn why older adults should be vaccinated against RSV-LRTD

Not an actual patient.

Vaccination may not protect all recipients.[1]

RSV=respiratory syncytial virus; RSV-LRTD=respiratory syncytial virus-associated lower respiratory tract disease.

AREXVY
(RESPIRATORY SYNCYTIAL VIRUS VACCINE, ADJUVANTED)

Important Safety Information

- AREXVY is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of AREXVY
- Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of AREXVY

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Please see additional Important Safety Information throughout and accompanying full Prescribing Information for AREXVY.

Understanding RSV

Older adults are at increased risk for severe RSV infection, including those with certain underlying conditions.[2]

RSV characteristics include[2-4]:

- **Prevalence during fall and winter, but may vary by region in the United States**
- **Presentation as mild, cold-like symptoms (which can become severe)**
- **Transmission through coughing or sneezing**

It's important to know: In older adults, severe symptoms consistent with a lower respiratory tract infection can occur.[2,5]

DO YOU HAVE PATIENTS AGED 60 YEARS AND OLDER?
Start a conversation about the risk of RSV, as well as vaccinating with AREXVY.

Not an actual patient.

Important Safety Information (cont.)

- Syncope (fainting) may occur in association with administration of injectable vaccines, including AREXVY. Procedures should be in place to avoid injury from fainting

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Please see additional Important Safety Information throughout and accompanying full Prescribing Information for AREXVY.

AREXVY provides exceptional efficacy for patients aged 60 years and older[1]

PRIMARY ENDPOINT

82.6%

Overall Efficacy Against RSV-LRTD

(96.95% CI, 57.9, 94.1)

AREXVY (7 cases out of 12,466), placebo (40 cases out of 12,494)

SECONDARY ENDPOINT

94.6%

Efficacy Against RSV-LRTD in Participants With at Least 1 Comorbidity*

(95% CI, 65.9, 99.9)

AREXVY (1 case out of 4937), placebo (18 cases out of 4861)

CI=confidence interval.

Study Design[1]:

Study 1, an ongoing, phase 3, randomized, placebo-controlled, observer-blind study in adults aged ≥60 years, evaluated the efficacy of AREXVY in preventing RSV-LRTD during the first season. Participants in the primary population for efficacy analysis received 1 dose of AREXVY (n=12,466) or placebo (n=12,494). At the time of this analysis, median follow-up was 6.7 months.

LRTD was defined as ≥2 lower respiratory symptoms/signs, including ≥1 lower respiratory sign for at least 24 hours, or ≥3 lower respiratory symptoms for at least 24 hours.

***Comorbidities of interest:** chronic obstructive pulmonary disease (COPD), asthma, any chronic respiratory/pulmonary disease, chronic heart failure, diabetes mellitus type 1 or type 2, and advanced liver or renal disease.

Important Safety Information (cont.)

- Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to AREXVY
- The most commonly reported adverse reactions (≥10%) were injection site pain (60.9%), fatigue (33.6%), myalgia (28.9%), headache (27.2%), and arthralgia (18.1%)

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A demonstrated safety profile[1]

Percentage of participants with solicited local and systemic adverse reactions within 4 days of vaccination in adults aged 60 years and older (solicited safety set with 4-day diary card)

	AREXVY %	Placebo[a] %
Local Adverse Reactions	**N=879**	**N=874**
Pain, Any[b]	60.9	9.3
Pain, Grade 3[b]	1	0
Erythema, >20 mm	7.5	0.8
Erythema, >100 mm	0.2	0
Swelling, >20 mm	5.5	0.6
Swelling, >100 mm	0.2	0
Systemic Adverse Reactions	**N=879**	**N=878**
Fatigue, Any[c]	33.6	16.1
Fatigue, Grade 3[c]	1.7	0.5
Myalgia, Any[c]	28.9	8.2
Myalgia, Grade 3[c]	1.4	0.3
Headache, Any[c]	27.2	12.6
Headache, Grade 3[c]	1.3	0
Arthralgia, Any[c]	18.1	6.4
Arthralgia, Grade 3[c]	1.3	0.6
Fever, ≥38.0 °C/100.4 °F[d]	2.0	0.3
Fever, >39.0 °C/102.2 °F[d]	0.1	0.1

STUDY DESIGN[1]:

Solicited AEs were evaluated in a subset of participants following a dose of AREXVY (n=879) or placebo (n=874). SAEs and pIMDs were monitored in all participants for 6 months following administration of AREXVY (n=12,467) or placebo (n=12,499), and AEs leading to deaths were monitored through the first analysis of Study 1.

Similar rates of SAEs (4.2% vs 4.0%), deaths (0.4% vs 0.5%), and pIMDs (0.3% vs 0.3%) were reported between AREXVY and placebo, respectively.[1]

N=exposed set for solicited safety set included all participants with at least 1 documented dose.

[a]Placebo was a saline solution.

[b]Any grade pain: Defined as any pain neither interfering with nor preventing normal everyday activities (Grade 1), painful when limb is moved and interferes with everyday activities (Grade 2), or significant pain at rest and prevents normal everyday activities (Grade 3).

[c]Any grade fatigue, myalgia, headache, arthralgia: Defined as event easily tolerated (Grade 1), interfering with normal activity (Grade 2), or preventing normal activity (Grade 3).

[d]Temperature taken by any route (oral, axillary, or tympanic).

AE=adverse event; pIMD=potential immune-mediated disease; SAE=serious adverse event.

Dosing and administration[1]

How is AREXVY dosed and administered?

AREXVY is supplied in 2 vials that must be reconstituted prior to administration

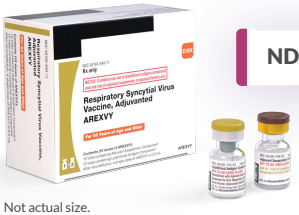
Administer 1 dose (0.5 mL) of AREXVY as an intramuscular injection

Please refer to the full Prescribing Information for AREXVY for full details.

Helpful tip

Talk to your patients about AREXVY when discussing seasonal influenza vaccine

Use the following code when billing AREXVY:



Not actual size.

NDC: 10-dose carton 58160-848-11

For payers who require NDCs in an 11-digit format, please use: 58160-0848-11

NDC=National Drug Code.

Important Safety Information (cont.)

- Vaccination with AREXVY may not result in protection of all vaccine recipients

(continued on page 6)

Please see additional Important Safety Information throughout and accompanying full Prescribing Information for AREXVY.

How AREXVY is prepared[1]

AREXVY is supplied in 2 vials that must be reconstituted prior to administration. Please refer to the full Prescribing Information for AREXVY for comprehensive details.

Prepare AREXVY by reconstituting the lyophilized antigen component (a sterile white powder) with the accompanying adjuvant suspension component (an opalescent, colorless to pale brownish sterile liquid). Use only the supplied adjuvant suspension component for reconstitution. The reconstituted vaccine should be an opalescent, colorless to pale brownish liquid. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.

STEP A: WITHDRAW
Cleanse both vial stoppers. Using a sterile needle and sterile syringe, withdraw the entire contents of the vial containing the adjuvant suspension component (liquid) by slightly tilting the vial. Vial 1 of 2.

STEP B: TRANSFER
Slowly transfer entire contents of syringe into the lyophilized antigen component vial (powder). Vial 2 of 2.

STEP C: SWIRL
Gently swirl the vial until the powder is completely dissolved. **DO NOT SHAKE VIGOROUSLY.**

STEP D: AFTER RECONSTITUTION
After reconstitution, withdraw 0.5 mL from the vial containing the reconstituted vaccine and administer intramuscularly.

Important Safety Information (cont.)

- AREXVY is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of AREXVY

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Storage[1]

AREXVY should be refrigerated. DO NOT FREEZE (discard if frozen)

Store in the original package to protect vials from light

Store adjuvant suspension component vials and lyophilized antigen component vials between 2 °C and 8 °C (36 °F and 46 °F) before reconstitution

After reconstitution, administer immediately or store between 2 °C and 8 °C (36 °F to 46 °F) or at room temperature up to 25 °C (77 °F) for up to 4 hours prior to use

Protect from light. Discard reconstituted vaccine if not used within 4 hours

Important Safety Information (cont.)

- Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of AREXVY

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Please see additional Important Safety Information throughout and accompanying full Prescribing Information for AREXVY.

RSV STOPS HERE

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TALK about the risk of RSV for adults aged 60 years and older, including those with certain underlying conditions, discuss the benefits of vaccinating against RSV-LRTD, and review the safety and efficacy of AREXVY.[1,2]

Learn more at AREXVYhcp.com

Questions about AREXVY?

Call 1-877-AREXVY1 (1-877-273-9891)
Available Monday-Friday
8:30 AM - 5:30 PM ET

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Please see additional Important Safety Information throughout and accompanying full Prescribing Information for AREXVY.

References: 1. Prescribing Information for AREXVY. **2.** RSV in older adults and adults with chronic medical conditions. Centers for Disease Control and Prevention. Accessed September 8, 2023. https://www.cdc.gov/rsv/high-risk/older-adults.html **3.** RSV surveillance and research. Centers for Disease Control and Prevention. Accessed September 8, 2023. https://www.cdc.gov/rsv/research/index.html **4.** RSV transmission. Centers for Disease Control and Prevention. Accessed September 8, 2023. https://www.cdc.gov/rsv/about/transmission.html **5.** Mesa-Frias M, Rossi C, Emond B, et al. Incidence and economic burden of respiratory syncytial virus among adults in the United States: a retrospective analysis using 2 insurance claims databases. *J Manag Care Spec Pharm.* 2022;28(7):753-765. doi:10.18553/jmcp.2022.21459

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