

RSV STOPS HERE

AREXVY 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;
- 18 through 59 years of age who are at increased risk for LRTD caused by RSV.

AREXVY is not for use in pregnant individuals.

Not an actual patient.

Vaccination may not protect all recipients.¹

Important Safety Information

- AREXVY is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of AREXVY
- The results of a postmarketing observational study suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination with AREXVY
- Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of AREXVY

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#) for AREXVY.

Strengthen Your
Recommendation
for AREXVY

AREXVY
(RESPIRATORY SYNCYTIAL VIRUS
VACCINE, ADJUVANTED)

Exceptional Efficacy for Your Patients Aged 60 Years and Older¹

STUDY 1: PRIMARY ENDPOINT¹

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)

STUDY 1: SECONDARY ENDPOINT¹

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)

At the time of this analysis, median follow-up was 6.7 months.¹

Study 1 Design¹: Study 1, a phase 3, randomized, placebo-controlled, observer-blind study in individuals aged ≥60 years, evaluated the efficacy of AREXVY in preventing RSV-LRTD for up to 3 RSV seasons. Participants in the primary population for efficacy analysis received 1 dose of AREXVY (N=12,466) or placebo (N=12,494).

RSV-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.¹

***Comorbidities of interest¹:** COPD, asthma, any chronic respiratory/pulmonary disease, chronic heart failure, diabetes mellitus type 1 or type 2, and advanced liver or renal disease.

COPD=chronic obstructive pulmonary disease; RSV-LRTD=respiratory syncytial virus-associated lower respiratory tract disease.

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

A Demonstrated Safety Profile¹

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

STUDY 1: SAFETY DATA

	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

In the solicited safety set, the local administration site adverse reactions reported with AREXVY had a median duration of 2 days, and the systemic adverse reactions reported with AREXVY had a median duration ranging between 1 and 2 days.¹

Similar rates of serious adverse events (4.2% vs 4.0%) and potential immune-mediated diseases (0.3% vs 0.3%) were reported between AREXVY (N=12,467) and placebo (N=12,499), respectively.¹

Deaths were reported in 0.9% and 0.9% of participants who received AREXVY (N=12,469) and placebo (N=12,503), respectively.¹

N=exposed set for solicited safety set included all participants with at least 1 documented dose and who completed their diary.

^aPlacebo was a saline solution.

^bAny 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).

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

^dTemperature taken by any route (oral, axillary, or tympanic).

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#) for AREXVY.

AREXVY Is the Only RSV Vaccine With Efficacy Data Available Through 3 Full Seasons¹⁻³

SECONDARY ENDPOINTS

**Seasons 1-3 Vaccine Efficacy for Adults
Aged ≥60 Years, With Median Follow-Up
of 30.6 Months Up to the End of the
Third Season¹**

RSV-LRTD Overall

62.9%

(97.5% CI, 46.7, 74.8)

AREXVY (48 cases out of 12,468),
placebo (215 cases out of 12,498)

Participants With at Least 1 Comorbidity of Interest*

64.7%

(95% CI, 45.1, 78.1)

AREXVY (25 cases out of 5014),
placebo (116 cases out of 4951)

***Comorbidities of interest¹:** COPD, asthma, any chronic respiratory/pulmonary disease, chronic heart failure, diabetes mellitus type 1 or type 2, and advanced liver or renal disease.

For Seasons 1-2 (median follow-up of 17.8 months), the vaccine efficacy for adults aged ≥60 years against RSV-LRTD overall was 67.2% (97.5% CI, 48.2, 80.0; 30/12,469 in AREXVY vs 139/12,498 in placebo) and 66.7% (95% CI, 41.8, 82.0; 16/4983 in AREXVY vs 72/4919 in placebo) in participants with at least 1 comorbidity of interest.^{1*}

Study 1 Design (Seasons 1-3) – Efficacy^{1,4}

Study 1 evaluated the efficacy of a single dose of AREXVY in preventing RSV-LRTD in adults aged ≥60 years over 3 seasons (median 30.6 months). Pre-Season 2, participants who received AREXVY were re-randomized to receive placebo (N=4991) or a second dose of AREXVY (N=4966). Participants who received placebo before Season 1 (N=12,498) received a second dose of placebo before Season 2 (N=10,031). Participants who received a second dose of AREXVY did not contribute to these efficacy analyses after receipt of Dose 2. The efficacy analysis up to the end of the third RSV season included participants who received a single dose of AREXVY before Season 1 (N=12,468); duplicate data from one participant was excluded from end of Season 3 analysis.

Important Safety Information (cont.)

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

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#) for AREXVY.

Effective for Patients 50-59 Years of Age Who Are at Increased Risk for RSV-LRTD¹

Effectiveness of AREXVY in individuals 50 through 59 years of age with chronic medical conditions* (Study 4) was assessed by a comparison of RSV neutralizing antibody responses induced by AREXVY in this age group to antibody responses of individuals 60 years of age and older. The comparison met the criteria for immunobridging.¹

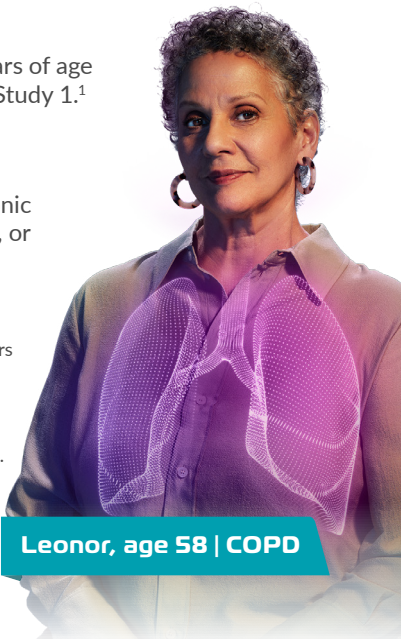
Vaccine efficacy in adults 60 years of age and older was demonstrated in Study 1.¹

*Medical conditions defined as¹:

chronic pulmonary disease, chronic cardiovascular disease, diabetes, or chronic kidney or liver disease.

Study 4 Design-Immunobridging¹:

In Study 4, individuals 50 through 59 years of age with chronic medical conditions* were randomized to receive AREXVY (N=386) or saline placebo (N=191). A comparator group of individuals 60 years and older also received AREXVY (N=381).



Leonor, age 58 | COPD

Not an actual patient.

Important Safety Information (cont.)

- Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to AREXVY
- In adults 60 years of age and older, the most commonly reported adverse reactions ($\geq 10\%$) were injection site pain (60.9%), fatigue (33.6%), myalgia (28.9%), headache (27.2%), and arthralgia (18.1%)

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#) for AREXVY.

Safety Profile for Participants Aged 50-59 Years¹

Percentage of participants with solicited local adverse reactions and systemic adverse reactions within 4 days of vaccination from Study 4 (exposed set)

STUDY 4: SAFETY DATA

	AREXVY 50-59 YOA %	Placebo ^a 50-59 YOA %
Local Adverse Reactions		
Pain, Any ^b	N=756 75.8	N=379 12.1
Pain, Grade 3 ^b	3.4	0.3
Erythema, >20 mm	13.2	0.5
Erythema, >100 mm	0.5	0
Swelling, >20 mm	10.4	0.8
Swelling, >100 mm	0.1	0
Systemic Adverse Reactions		
Fatigue, Any ^c	N=756 39.8	N=380 18.2
Fatigue, Grade 3 ^c	2.8	0.8
Myalgia, Any ^c	35.6	9.7
Myalgia, Grade 3 ^c	2.5	0.5
Headache, Any ^c	31.7	16.8
Headache, Grade 3 ^c	2.6	1.1
Arthralgia, Any ^c	23.4	7.9
Arthralgia, Grade 3 ^c	1.7	0.8
Fever, $\geq 38.0^\circ\text{C}/100.4^\circ\text{F}^d$	3.2	1.1
Fever, $>39.0^\circ\text{C}/102.2^\circ\text{F}^d$	0.1	0.5

The median duration of solicited local and systemic adverse reactions after vaccination with AREXVY was 2-3 days and 1-2 days, respectively.¹

The rates of solicited local and systemic adverse reactions were similar in participants 50-59 years of age with or without medical conditions associated with an increased risk of RSV-LRTD.¹

Among participants 50-59 years of age, serious adverse events (2.3% vs 2.1%), deaths (0.5% vs 0.3%), and potential immune-mediated diseases (0.5% vs 0.3%) were reported after receiving AREXVY (N=769) or placebo (N=383), respectively.¹

YOA=years of age.

N=exposed set included all participants with at least 1 documented dose and with completed diary card.

^aPlacebo was a saline solution.

^bAny 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).

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

^dTemperature taken by any route (oral or axillary).

Effective for Patients 18-49 Years of Age Who Are at Increased Risk for RSV-LRTD¹

Effectiveness of AREXVY in individuals 18 through 49 years of age with chronic medical conditions* (Study 7) was assessed by a comparison of RSV neutralizing antibody responses induced by AREXVY in this age group to antibody responses of individuals 60 years of age and older. The comparison met the criteria for immunobridging.¹

Vaccine efficacy in adults 60 years of age and older was demonstrated in Study 1.¹

*Medical conditions defined as¹:

chronic pulmonary disease, chronic cardiovascular disease, diabetes, chronic liver disease, chronic kidney disease, or neurological or neuromuscular conditions.

Study 7 Design-Immunobridging¹:

In Study 7, individuals 18 through 49 years of age at increased risk of RSV-LRTD due to certain chronic medical conditions* were enrolled to receive 1 dose of AREXVY (N=426). A comparator group of individuals 60 years and older also received 1 dose of AREXVY (N=429).

Important Safety Information (cont.)

- In adults 50 through 59 years of age, the most commonly reported adverse reactions (≥10%) were injection site pain (75.8%), fatigue (39.8%), myalgia (35.6%), headache (31.7%), arthralgia (23.4%), erythema (13.2%), and swelling (10.4%)
- In adults 18 through 49 years of age, the most commonly reported adverse reactions (≥10%) were injection site pain (76.0%), myalgia (59.9%), fatigue (59.6%), headache (43.6%), and arthralgia (28.3%)

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#) for AREXVY.

Safety Profile for Participants Aged 18-49 Years¹

Percentage of participants with solicited local adverse reactions and systemic adverse reactions within 4 days of vaccination from Study 7 (exposed set)

AREXVY 18-49 YOA %

Local Adverse Reactions N=1026	
Pain, Any ^a	76.0
Pain, Grade 3 ^a	1.3
Erythema, >20 mm	8.6
Erythema, >100 mm	0.2
Swelling, >20 mm	7.0
Swelling, >100 mm	0.2
Systemic Adverse Reactions N=1027	
Fatigue, Any ^b	59.6
Fatigue, Grade 3 ^b	3.0
Myalgia, Any ^b	59.9
Myalgia, Grade 3 ^b	2.1
Headache, Any ^b	43.6
Headache, Grade 3 ^b	2.1
Arthralgia, Any ^b	28.3
Arthralgia, Grade 3 ^b	1.2
Fever, ≥38.0 °C/100.4 °F ^c	5.0
Fever, >39.0 °C/102.2 °F ^c	1.1

The median duration of solicited local and systemic adverse reactions after AREXVY vaccination was 2-3 days and 1-2 days, respectively.¹

Within 6 months postvaccination, among participants 18 through 49 years of age who received AREXVY (N=1029), no serious adverse events related to vaccination were reported, while 0.2% of participants reported new onset potential immune-mediated diseases or exacerbation of existing potential immune-mediated diseases.¹

N=exposed set included all participants with at least 1 documented dose and with available data.

^aAny 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).

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

^cTemperature taken by any route (oral or axillary).

The CDC Recommendation for RSV Vaccination in Adults

The CDC recommends⁵:



- **Adults 50-74 years of age who are at increased risk of severe RSV illness*** receive a single dose of RSV vaccine
- **Adults 75 years of age and older** receive a single dose of RSV vaccine

*See right side for CDC-identified risk factors for severe RSV illness.

Additional information from the CDC⁵

Eligible adults are currently recommended to receive a single dose of RSV vaccine; adults who have already received RSV vaccination should not receive another dose. Eligible adults may be vaccinated at any time of year, but vaccination will have the most benefit if administered in late summer or early fall, just before the RSV season.

CDC=Centers for Disease Control and Prevention.

Important Safety Information (cont.)

- AREXVY is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of AREXVY
- The results of a postmarketing observational study suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination with AREXVY

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information for AREXVY](#).

List of CDC-Identified Risk Factors for Severe RSV Illness⁵

Qualified vaccinators, including pharmacists, nurse practitioners, and other providers (based on state and jurisdictional law) may determine patient eligibility for RSV vaccination based on clinical assessment even in the absence of medical documentation of a named risk condition. Patient attestation is sufficient evidence of the presence of a risk factor; vaccinators should not deny RSV vaccination to a person because of lack of documentation.^{3,5}



Chronic lung
or respiratory disease



Chronic
cardiovascular
disease



Chronic liver disease



Residence in a
nursing home



End-stage renal disease
or dialysis dependence
or other renal replacement
therapy



Moderate or severe
immune compromise



Diabetes mellitus complicated by chronic kidney disease,
neuropathy, retinopathy, or other end-organ damage,
or requiring treatment with insulin or SGLT2 inhibitor

Other factors include:

- Neurologic or neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness
- Chronic hematologic conditions
- Severe obesity (body mass index ≥ 40 kg/m²)
- Other chronic medical conditions or risk factors that a healthcare provider determines would increase the risk for severe disease due to viral respiratory infection (eg, frailty)

Data on the safety and efficacy of AREXVY in individuals with these risk factors for severe RSV illness as described by the CDC may be limited.¹

SGLT2=sodium-glucose cotransporter-2.

Coadministration of AREXVY With Other Adult Vaccines

- According to the US Prescribing Information, AREXVY can be coadministered with flu vaccination¹
- According to the CDC, RSV vaccines can be coadministered with other adult vaccines during the same visit⁵
- Data on immunogenicity of RSV vaccines and other vaccines when coadministered are currently limited⁵
- Coadministration of RSV vaccine with one or more adult vaccines during the same visit may increase common side effects⁵

Help Facilitate the Vaccination Process for Your Patients

A suite of resources to help guide your patients

- Easyvax vaccine scheduler tool
- Electronic prescription sent from EHR to your patients' pharmacy
- Paper scripts for your patients
- Patient handouts with vaccination information*
- "What to Expect" resource that outlines the clinical information for AREXVY*



easyvax 

*Contact your GSK sales representative for this resource.
EHR=electronic health record.

Important Safety Information (cont.)

- Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of AREXVY
- Syncope (fainting) may occur in association with administration of injectable vaccines, including AREXVY. Procedures should be in place to avoid injury from fainting

A Recommendation From Their HCP Is the Strongest Predictor of Adults Getting Vaccinated⁶

STEP 1: DISCUSS THE IMPACT OF RSV

- Identify and discuss factors that put patients at increased risk for severe RSV illness, including older age and certain comorbidities⁷
- Discuss the risk of complications with severe RSV⁸

STEP 2: RECOMMEND AREXVY

- Review efficacy data and established safety profile of AREXVY with patients who may be at increased risk for severe RSV illness
- Help patients assess the risks and benefits of vaccination
- Provide a personalized recommendation for AREXVY

STEP 3: SUPPORT VACCINATION

- Send an e-script to the patient's pharmacy of choice and help schedule their vaccination appointment through easyvax online today
- Follow up with your patient's pharmacist to ensure they received AREXVY

Important Safety Information (cont.)

- Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to AREXVY

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#) for AREXVY.

Download helpful resources
at AREXVYhcp.com



Important Safety Information (cont.)

- In adults 60 years of age and older, the most commonly reported adverse reactions ($\geq 10\%$) were injection site pain (60.9%), fatigue (33.6%), myalgia (28.9%), headache (27.2%), and arthralgia (18.1%)
- In adults 50 through 59 years of age, the most commonly reported adverse reactions ($\geq 10\%$) were injection site pain (75.8%), fatigue (39.8%), myalgia (35.6%), headache (31.7%), arthralgia (23.4%), erythema (13.2%), and swelling (10.4%)
- In adults 18 through 49 years of age, the most commonly reported adverse reactions ($\geq 10\%$) were injection site pain (76.0%), myalgia (59.9%), fatigue (59.6%), headache (43.6%), and arthralgia (28.3%)
- Vaccination with AREXVY may not result in protection of all vaccine recipients

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#) for AREXVY.

References: **1.** Prescribing Information for AREXVY. **2.** Walsh EE, Pérez Marc G, Falsey AR, et al. RENOIR trial – RSVpreF vaccine efficacy over two seasons. *N Engl J Med.* 2024;391(15):1459-1460. doi:10.1056/nejmc2311560 **3.** Britton A, Roper LE, Kotton CN, et al. Use of respiratory syncytial virus vaccines in adults aged ≥ 60 years: updated recommendations of the Advisory Committee on Immunization Practices – United States, 2024. *MMWR.* 2024;73(32):696-702. doi:10.15585/mmwr.mm7332e1 **4.** Ison MG, Papi A, Athan E, et al. Efficacy and safety of respiratory syncytial virus prefusion F protein vaccine (RSVPreF3 OA) in older adults over 2 RSV seasons. *Clin Infect Dis.* 2024;78(6):1732-1744. doi:10.1093/cid/ciae010 **5.** Respiratory syncytial virus infection (RSV). RSV vaccine guidance for adults. Centers for Disease Control and Prevention. Reviewed February 24, 2026. Accessed June 3, 2026. <https://www.cdc.gov/rsv/hcp/vaccine-clinical-guidance/adults.html> **6.** Adult immunization standards. Centers for Disease Control and Prevention. Reviewed August 9, 2024. Accessed June 3, 2026. <https://www.cdc.gov/vaccines-adults/hcp/imz-standards/> **7.** Respiratory syncytial virus infection (RSV). RSV in adults. Centers for Disease Control and Prevention. Reviewed February 20, 2026. Accessed June 3, 2026. <https://www.cdc.gov/rsv/adults/> **8.** Respiratory syncytial virus infection (RSV). Clinical overview of RSV. Centers for Disease Control and Prevention. Reviewed August 18, 2025. Accessed June 23, 2026. <https://www.cdc.gov/rsv/hcp/clinical-overview/>

Trademarks are owned by or licensed
to the GSK group of companies.

©2026 GSK or licenssor.

PMUS-RSABROC260010 June 2026

Produced in USA. 0002-0048-44

AREXVY
(RESPIRATORY SYNCYTIAL VIRUS
VACCINE, ADJUVANTED)

GSK