Important Drug Safety Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC25-005-CG
January 16, 2025

FDA announced that, FDA has required and approved safety labeling changes to the Prescribing Information for Abrysvo (Respiratory Syncytial Virus Vaccine) manufactured by Pfizer Inc. and Arexvy (Respiratory Syncytial Virus Vaccine, Adjuvanted) manufactured by GlaxoSmithKline Biologicals. Specifically, FDA has required each manufacturer to include a new warning about the risk for Guillain-Barré syndrome (GBS) following administration of their Respiratory Syncytial Virus (RSV) vaccine. The Prescribing Information for each vaccine has been revised to include the following language in the Warnings and Precautions section:

About Abrysvo: Abrysvo was initially approved on May 31, 2023, for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older. Subsequently, FDA has approved the vaccine for the following: prevention of LRTD caused by RSV in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV; immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age.

About Arexvy: Arexvy was initially approved on May 3, 2023, for the prevention of LRTD caused by RSV in individuals 60 years of age and older. Subsequently, FDA has approved the vaccine for use in individuals 50 through 59 years of age who are at increased risk for LRTD caused by RSV.

RECOMMENDATIONS

1. Suspected adverse events may be reported to (VAERS) (https://vaers.hhs.gov/reportevent.html), which is co-managed by the FDA and the Centers for Disease Control and Prevention (CDC).

2. Expect patients to visit your pharmacy asking for information on this safety issue and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

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FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Requires Guillain-Barré Syndrome (GBS) Warning in the Prescribing Information for RSV Vaccines Abrysvo and Arexvy: FDA Safety Communication

[Posted 1/7/2025]

AUDIENCE: Patient, Health Care Professional, Pharmacy, Immunology, Pulmonology

ISSUE: FDA has required and approved safety labeling changes to the Prescribing Information for Abrysvo (Respiratory Syncytial Virus Vaccine) manufactured by Pfizer Inc. and Arexvy (Respiratory Syncytial Virus Vaccine, Adjuvanted) manufactured by GlaxoSmithKline Biologicals. Specifically, FDA has required each manufacturer to include a new warning about the risk for Guillain-Barré syndrome (GBS) following administration of their Respiratory Syncytial Virus (RSV) vaccine. The Prescribing Information for each vaccine has been revised to include the following language in the Warnings and Precautions section:

Abrysvo - The results of a postmarketing observational study suggest an increased risk of Guillain-Barré syndrome (GBS) during the 42 days following vaccination with Abrysvo.

Arexvy - The results of a postmarketing observational study suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination with Arexvy.

BACKGROUND: GBS is a rare disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis.

About Abrysvo

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About Arexvy

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