COMMUNICATION

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Safety Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug safety information.

U.S. Food & Drug Administration Publication Date:

1/7/2025

Drug Indication:

Prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV)

Safety Topic:

The FDA has required and approved safety labeling changes to the Prescribing Information for Abrysvo™ (Respiratory Syncytial Virus Vaccine) and Arexvy™ (Respiratory Syncytial Virus Vaccine, Adjuvanted).

FDA Requires Guillain-Barré Warning for Abrysvo™ and Arexvy™

It is for this reason that we are notifying you that on 1/7/2025 the U.S. Food and Drug Administration (FDA) published a safety communication for the following product(s): Abrysvo™ (Respiratory Syncytial Virus Vaccine) and Arexvy™ (Respiratory Syncytial Virus Vaccine, Adjuvanted).

Reason for Communication:

The FDA carried out a post-marketing observational study to evaluate the risk of Guillain-Barré Syndrome (GBS) after receiving the Abrysvo and Arexvy vaccines. After reviewing data from clinical trials, reports to the Vaccine Adverse Event Reporting System (VAERS), and the post-marketing study, the FDA concluded that the overall evidence points to an increased risk of GBS with both Abrysvo and Arexvy. However, the available data is insufficient to establish a causal relationship. The labels for both Abrysvo, manufactured by Pfizer, and Arexvy, manufactured by GSK, have been updated to include to say “postmarketing observational study suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination.”

Background Information:

Guillain-Barré syndrome is a neurological condition where the immune system mistakenly targets components of the peripheral nervous system, leading to muscle weakness and, in some cases, paralysis.

Both vaccines received approval in May 2023 for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals aged 50 and older. Additionally, Abrysvo is authorized for use in pregnant women to help prevent RSV in newborns.

It is important to note that the benefits of vaccination with Abrysvo and Arexvy continue to outweigh their risks.

Remember you can report adverse events related to vaccines at Vaccine Adverse Event Reporting System (VAERS) by any of the following ways:

Complete and submit the report online.

Report using a writable PDF form and then uploading to the website. If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report, you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- ext. 219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

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REFERENCES

1. U.S. Food and Drug Administration. (2025). *FDA requires Guillain-Barré syndrome (GBS) warning in prescribing information for RSV vaccines Abrysvo and Arexvy*. U.S. Food and Drug Administration. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-requires-guillain-barre-syndrome-gbs-warning-prescribing-information-rsv-vaccines-abrysvo-and
2. U.S. Department of Health & Human Services. (n.d.). *Vaccine Adverse Event Reporting System (VAERS).* U.S. Department of Health & Human Services. Retrieved January 13, 2025, from https://vaers.hhs.gov/index.html

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