

# GSK and Pfizer's RSV vaccines to carry warnings of neurological disorder risk

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Bengaluru: GSK and Pfizer's respiratory syncytial virus (RSV) vaccines will carry warnings that they can increase the risk of developing a rare neurological disorder, the U.S. Food Drug

Administration said on Tuesday.

The regulator conducted a postmarketing trial which suggested increased risk of Guillain-Barre syndrome (GBS) 42 days following vaccination.

However, the available evidence was insufficient to establish a causal relationship, the FDA said.

The risks flagged in the prescribing information of GSK's Arexvy and Pfizer's Abrysvo were not the regulator's strictest "boxed" warnings.

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In Arexvy's clinical trial, a participant had developed GBS after receiving the vaccine, while in Abrysvo's trial, one participant developed the disease and another got a variant of it.

Last year, advisers to the U.S. Centers for Disease Control and Prevention had postponed endorsing Arexvy's use in the 50-59 age group. They had also flagged the risk of GBS.

**News Source:**

<https://pharma.economictimes.indiatimes.com/news/pharma-industry/gsk-and-pfizers-rsv-vaccines-to-carry-warnings-of-neurological-disorder-risk/117041421>