SFDA

Safety Communication

[31/07/2025]

Risk of Guillain-Barré Syndrome Following Vaccination with Respiratory Syncytial Virus Vaccines (ABRYSVO® and AREXVY®) in older adults

The Saudi Food and Drug Authority (SFDA) would like to inform healthcare professionals about a potential risk of Guillain-Barré syndrome (GBS) following the use of two respiratory syncytial virus (RSV) vaccines: ABRYSVO® (bivalent, recombinant), AREXVY® (recombinant, adjuvanted) .This risk has been observed in adults aged 60 years and older.

- *AREXVY® is approved for active immunization to prevent lower respiratory tract disease caused by RSV in adults aged 60 years and older and adults aged 50 -59 years who are at increased risk for RSV disease.*
- *ABRYSVO ® is approved for passive protection against lower respiratory tract disease caused by RSV in infants (from birth through 6 months of age) following maternal immunization during pregnancy (between weeks 24 and 36 of gestation) and for active immunization of individuals aged 18 years and older for the prevention of lower respiratory tract disease caused by RSV.*

GBS is a rare but serious neurological disorder where the immune system attacks peripheral nerves. It may result in muscle weakness, numbness, and in severe cases, paralysis. Symptoms

may include: tingling or weakness in the legs, arms, or face, difficulty walking or facial drooping, shortness of breath or chest discomfort, loss of reflexes.

As part of ongoing pharmacovigilance activities, the SFDA has reviewed published literature and post marketing safety databases concerning the potential risk of GBS with RSV vaccines. There are several global cases reported of GBS were reported following the use of ABRYSVO® and AREXVY® and no local cases have been reported to the SFDA. The available evidence suggests a potential increased risk of GBS during the 42 days post vaccination with ABRYSVO® and AREXVY®, in individuals 65 years of age and older.
The local product information of ABRYSVO® already includes a warning regarding the potential risk of GBS in older adults. The SFDA has requested the Marketing Authorization Holder of AREXVY® to update the local product information to include the risk of GBS in adults aged 60 years and older.

The SFDA provides the following recommendations for healthcare professionals:

- Inform recipients of ABRYSVO® and AREXVY® about the signs and symptoms of GBS and emphasize the importance of seeking immediate medical care if symptoms occur.
- Closely monitor vaccinated individuals for any neurological symptoms, especially during the 42 days post RSV vaccination.
- Report all suspected adverse events, including GBS, to the National Pharmacovigilance Centre (NPC) at the SFDA.

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):

SFDA Call Center: 19999

E-mail: npc.drug@sfda.gov.sa

Website: https://ade.sfda.gov.sa

aRMM: