The United Kingdom: Abrysvo▼(Pfizer RSV vaccine) and Arexvy▼(GSK RSV vaccine): be alert to a small risk of Guillain-Barré syndrome following vaccination in older adults

Medicines and Healthcare products Regulatory Agency (MHRA) announces that there is a small increase in the risk of Guillain-Barré syndrome following vaccination with Abrysvo (Pfizer respiratory syncytial virus (RSV) vaccine) and Arexvy (GSK RSV vaccine) in adults aged 60 years and older. Healthcare professionals should advise all recipients of Abrysvo and Arexvy that they should be alert to signs and symptoms of Guillain-Barré syndrome and, if they occur, to seek immediate medical attention as it requires urgent treatment in hospital.

There is currently no evidence of an increased risk of Guillain-Barré syndrome in pregnant women following vaccination with Abrysvo, the only RSV vaccine approved for use during pregnancy. The Commission on Human Medicines (CHM) advise that the benefits of vaccination against RSV outweigh the small risk of developing Guillain-Barré syndrome in older adults.

Advice for Healthcare Professionals:

- there is a small increase in the risk of Guillain-Barré syndrome following vaccination with Abrysvo and Arexvy in adults (aged 60 years and older). Currently, there is no evidence of an increased risk of Guillain-Barré syndrome in pregnant women following vaccination with Abrysvo, the only RSV vaccine approved for use during pregnancy
- be attentive to signs and symptoms of Guillain-Barré syndrome in all recipients of Abrysvo and Arexvy to ensure early and correct diagnosis, initiate adequate supportive care and treatment, and rule out other causes
- early medical care can reduce severity and improve outcomes

Advice for Healthcare Professionals to Provide to Patients:

- the RSV vaccine helps protect against respiratory syncytial virus (RSV), a virus which can make older adults and babies seriously ill. RSV can cause a type of chest infection called bronchiolitis in babies which can cause breathing problems and may need to be treated in hospital. RSV can also cause a serious lung infection (pneumonia) in and older adults requiring hospital care in some cases
- the Pfizer RSV vaccine Abrysvo is currently offered in NHS vaccination programmes against RSV to adults aged 75-79 years old and to pregnant women to help protect babies after they are born
- the GSK RSV vaccine Arexvy is not currently available on the NHS but may be available privately for use in individuals aged 60 years and older, or those aged 50–59 years who are at increased risk of RSV disease; Arexvy should not be given to pregnant individuals
- rare or very rare cases of Guillain-Barré syndrome have been reported in older adults who have received the Abrysvo or Arexvy RSV vaccines respectively. Currently, there is no evidence that the Abrysvo RSV vaccine increases the risk of Guillain-Barré syndrome in pregnant women
- Guillain-Barré syndrome is a serious nerve condition. It usually affects your arms and legs first before you get symptoms in other parts of your body

- you might feel tingling, numbness or pins and needles in your feet and hands first. This is usually followed by muscle weakness and difficulty moving your joints
- other symptoms can include:
    - tingling, numbness or pins and needles in your feet and hands
    - muscle weakness and difficulty moving your joints
    - sharp, shooting pain (nerve pain), often in your legs or back
    - problems breathing
    - problems with your face, such as drooping face muscles or trouble swallowing or speaking
    - problems with your eyes, such as double vision
- some people's symptoms become so severe that they are not able to move their legs, arms and face (paralysis)
- urgent hospital treatment is required to help prevent the symptoms progressing and improve recovery, however the effects of Guillain-Barré syndrome may sometimes be long-lasting
- seek immediate medical attention if you notice signs of Guillain-Barré syndrome

Background

NHS vaccination programmes against RSV

Respiratory syncytial virus (RSV) is an infectious disease of the airways and lungs. RSV infection is common in young children but is most serious for small babies and for older people. Abrysvo (Pfizer RSV vaccine) is currently being used in NHS vaccination programmes against RSV in older adults aged 75 to 79 years old and in pregnant women to protect their infants.

Risk of Guillain-Barré syndrome in older adults following RSV vaccine

An increase in the risk of Guillain-Barré syndrome has been observed following vaccination with Abrysvo and Arexvy in adults aged 60 years and older.

Up to 2 June 2025, the MHRA received 21 Yellow Card reports of suspected Guillain-Barré syndrome in older adults (75-79 years, where known) following Abrysvo. This is in the context of over 1.9 million doses of Abrysvo administered in the older adult RSV vaccination programme up to 26 May 2025. Over the same time period, the MHRA has not received any Yellow Card reports of suspected Guillain-Barré syndrome following Arexvy however there has been very limited use of this vaccine in the UK to date as Arexvy (GSK RSV vaccine) is not currently deployed by the NHS.

A post-marketing observational study in the United States in individuals aged 65 years and older estimated that Abrysvo and Arexvy were associated with 9 and 7 excess Guillain-Barré syndrome cases per million vaccine doses administered, respectively. Preliminary unpublished post-marketing study data from the UK Health Security Agency and Public Health Scotland studies in adults aged 75-79 years estimate a combined excess of 15-25 Guillain-Barré syndrome cases per million vaccine doses of Abrysvo administered across England and Scotland. The risk of experiencing Guillain-Barré syndrome following Abrysvo in older adults remains rare. No UK post-marketing study data for Arexvy are available.

The new UK data regarding Abrysvo were reviewed by the Commission on Human Medicines (CHM) who advised that the benefits of the vaccine outweighed the risk of developing Guillain-Barré syndrome in older adults.

Risk of Guillain-Barré syndrome in pregnancy following Abrysvo

Abrysvo is the only RSV vaccine indicated for use during pregnancy to protect infants. Up to 2 June 2025, the MHRA has not received any Yellow Card reports of suspected Guillain-Barré syndrome in pregnant individuals following Abrysvo. This is in the context of over a quarter of million doses of Abrysvo administered in the pregnancy RSV vaccination programme up to 26 May 2025.

Currently, there is no evidence of an increase in the risk of Guillain-Barré syndrome following Abrysvo in pregnant individuals from either UK or world-wide data.

Product information for patients and healthcare professionals

The Summary of Product Characteristics (SmPC) and the Patient Information Leaflet (PIL) for Abrysvo and Arexvy contain warnings about the risk of Guillain-Barré syndrome. Guillain-Barré syndrome is also listed as possible side effect in older adults in the product information for these vaccines.

Please refer to the following website in MHRA for details:
http://www.gov.uk/drug-safety-update/abrysvov-pfizer-rsv-vaccine-and-arexvyv-gsk-rsv-vaccine-be-alert-to-a-small-risk-of-guillain-barre-syndrome-following-vaccination-in-older-adults

In Hong Kong, Abrysvo Vaccine Powder And Solvent For Solution For Injection (HK-68213) and Arexvy Vaccine Powder And Suspension For Suspension For Injection (HK-67997) are pharmaceutical products registered by Pfizer Corporation Hong Kong Limited and GlaxoSmithKline Limited, respectively. Both are prescription-only medicines. So far, the Department of Health (DH) has received one case of adverse event following immunisation with Arexvy, but this case was not reported as GBS. The DH has not received any case of adverse event following immunisation with Abrysvo.

Related news was previously issued by the US Food and Drug Administration and Australia Therapeutic Goods Administration, and was posted on the Drug Office website on 8 Jan 2025 and 19 May 2025. Letters to inform local healthcare professionals were issued by the DH on 8 Jan 2025. As previously reported, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

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