Abrysvo® respiratory syncytial virus (RSV) vaccine



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RSV immunisation

RSV infection can occur at any age, however the risks of severe illness and complications from RSV are increased in young infants and older adults.

On 7th June 2023, JCVI recommended that a universal immunisation programme should be developed to protect both infants and older adults.

From 1 September 2024, the RSV vaccine should be offered to:

- all pregnant women from 28 weeks' gestation
- **adults turning 75 years old**
- **adults aged 75 years up until their 80th birthday*** (one-off catch up)

The RSV vaccine should be offered throughout the year as this is a year-round programme.

Abrysvo® RSV vaccine

- Abrysvo® is a recombinant (DNA), bivalent RSV vaccine, containing recombinant RSV prefusion F protein (pre-F) antigens developed from each of the respiratory syncytial virus subtypes, A and B

- Abrysvo® is the only vaccine licensed for RSV vaccine currently available for use in Northern Ireland

- Abrysvo® is an inactivated (or non-live) vaccine

Vaccine schedule and dose

- single dose given to individuals on, or shortly after, their 75th birthday (remain eligible up until day before 80th birthday)

- one off catch up programme in 2024/25 – single dose given to all adults aged 75 to 79 years old on the 1 September 2024 (individuals aged 80 years old in the first year of the programme will be eligible until 31st August 2025)

- **a single dose is 0.5 ml** (the full volume of the reconstituted vaccine)

- Abrysvo ® should be administered immediately after reconstitution*, or within 4 hours if stored between 15°C and 30°C

Vaccine storage

- Abrysvo® should be stored in a vaccine fridge between +2°C and +8°C
- on arrival in the practice, the vaccine should be placed immediately in a vaccine / medication fridge
- the vaccine must not be frozen
- Abrysvo® should be stored in the original packaging to protect it from light
- further information on vaccine storage and stability is available in the Summary of Product Characteristics (SPC) and the vaccine specific Patient Group Direction (PGD)

Vaccine pack contents

Abrysvo® is presented as a single dose pack for reconstitution.

Each pack contains:

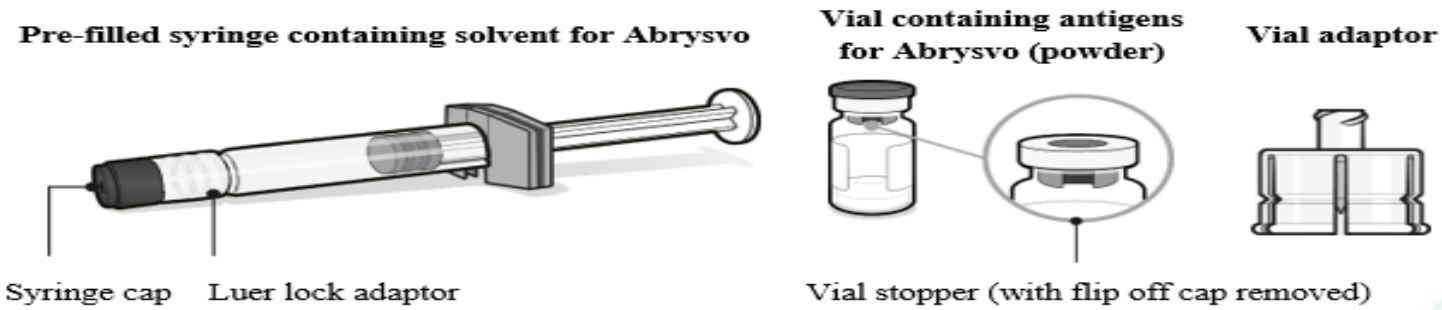
- powder for 1 dose in a vial
- solvent (water for injection) in a pre-filled glass syringe with a stopper, luer lock adaptor and tip cap
- vial adaptor
- 25G 25mm needle (suitable alternatives can be used if required).



Reconstitution (preparation) of Abrysvo® vaccine

Abrysvo® must be reconstituted prior to administration by adding the entire contents of the pre-filled syringe of solvent to the vial containing the powder, using the vial adaptor.

The vaccine must be reconstituted only with the solvent provided.



Clear instructions on how to prepare the vaccine for administration can be found in the Summary of Product Characteristics and the manufacturer's video. **Vaccinators are strongly encouraged to watch the video in its entirety before preparing the vaccine for the first time.**

Contraindications and precautions

- Abrysvo® should not be given to anyone who has had a confirmed anaphylactic reaction to a previous dose of an RSV vaccine, or any of the excipients (ingredients) in the vaccine
- for a full list of ingredients please refer to the Summary of Product Characteristics
- minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation
- however, if an individual is acutely unwell, immunisation may be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine

Adverse reactions following vaccination

Vaccines can cause side effects (also referred to as adverse reactions). Reactions occur because vaccines work by triggering an immune system response. Most side effects are mild and only last a few days.

Very common side effects following RSV vaccination include:

- injection site pain (41%)
- headache (31%)
- myalgia (muscle pains and aches) (27%).

A small number of cases of Guillain-Barré syndrome (GBS) were detected in phase 3 clinical trials and in post-marketing surveillance of older adults in the USA.

Co-administration

- RSV vaccines can be co-administered with Shingrix and pneumococcal vaccines in older adults
- some data indicate that, in older adults, administering Abrysvo® at the same time as seasonal influenza vaccine may reduce the immune response to the RSV vaccine and vice versa
- co-administration with COVID-19 vaccine may also reduce the immune response to RSV vaccine
- therefore, it is not recommended to routinely schedule RSV, flu and COVID-19 vaccine at the same appointment or on the same day
- however, no specific interval is required between administering the vaccines
- and, if it is thought that the individual is unlikely to return for a second appointment or immediate protection is necessary, Abrysvo® can be administered at the same time as influenza and/or COVID-19 vaccination

Further resources (RSV)

National RSV programme guidance Green Book on Immunisation chapter 27a Respiratory syncyntial virus (RSV) (publishing.service.gov.uk)

PHA Healthcare factsheet Health professional resources | HSC Public Health Agency (hscni.net)

E-learning Immunisation - elearning for healthcare (e-lfh.org.uk)

Abrysvo® (Pfizer) vaccine preparation instructional video

UKHSA RSV vaccination programme resources Respiratory syncytial virus (RSV) vaccination programme - GOV.UK (www.gov.uk)

Flu vaccines







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Flu vaccines 2024/25

- Adjuvanted quadrivalent flu vaccine (aQIV): Fluad Tetra® - adults aged 65 years and over

- Live attenuated influenza vaccine (LAIV): Fluenz® - children and adolescents aged 2 – 17 years unless contraindicated

- Cell-based quadrivalent inactivated flu vaccine (QIVc): Flucelvax Tetra® - children aged 6 months – 2 years / adults aged 18 - 64 / all other cohorts *(when first line contraindicated or otherwise unsuitable)*

Changes to the LAIV for the 2024 to 2025 flu vaccination programme

- when LAIV was first introduced into the annual flu vaccination programme for children in 2013, the vaccine was a trivalent vaccine which contained two type A and one type B influenza virus strains

- in 2014, LAIV was manufactured as a quadrivalent vaccine, Fluenz Tetra®, which was used in NI for the next ten flu seasons

- for the 2024/25 flu vaccination programme, the LAIV will be a trivalent vaccine again, Fluenz®

- this follows a recommendation from the WHO in 2023 that the B/Yamagata lineage antigen should be excluded from future influenza vaccines as there have been no confirmed naturally occurring B/Yamagata lineage virus detections after March 2020

- the trivalent vaccine will offer the same level of protection against the two A and one B flu virus strains in it as the quadrivalent vaccine and the inactivated flu vaccines are likely to become trivalent vaccines in future flu seasons

Contraindications (inactivated flu vaccines)

There are very few individuals who cannot receive any flu vaccines.

None of the influenza vaccines should be given to those who have had:

- confirmed anaphylactic reaction to a previous dose of the vaccine
- confirmed anaphylactic reaction to any component of the vaccine (except ovalbumin - see precautions).

The aQIV (Fluad Tetra®) is contraindicated in individuals with an egg allergy – see slides on egg allergy.

Always refer to SPC for individual products when deciding which vaccine to give.

Contraindications live attenuated flu vaccine (LAIV)

In addition, the live attenuated flu vaccine (Fluenz®) should not be given to children who are:

- clinically severely immunodeficient due to conditions or immunosuppressive therapy, such as:
  - acute and chronic leukaemias
  - lymphoma
  - HIV infection not suppressed by antiretroviral therapy
  - cellular immune deficiencies
  - high dose corticosteroids
- receiving salicylate therapy (other than for topical treatment of localised conditions) - association of Reye's syndrome with salicylates and wild-type influenza infection
- known to be pregnant.

Precautions to flu vaccines

Defer LAIV, or consider suitable alternative, such as inactivated flu vaccine (QIVc), if;

- acutely unwell (with systemic illness)
- heavy nasal congestion
- acute wheeze / exacerbation of asthma within last 72 hours
- recent antiviral medication (48 hours)
- cochlear implants (1 week pre surgery / 2 weeks post surgery / avoid if ongoing CSF leak).

Children who require regular oral steroids for maintenance of asthma control, or have previously required intensive care for asthma exacerbation should only be given LAIV on the advice of their specialist.

Egg allergy

- aQIV (Fluad Tetra) is contraindicated in individuals with a history of egg allergy

- LAIV should not be given to children with a history of egg allergy that required **admission to intensive care for a previous severe anaphylaxis to egg**

- children with an egg allergy that did not result in an intensive care admission can be safely vaccinated with LAIV in any setting

- QIVc (Flucelvax Tetra, cell based) should be the preferred option for patients aged 65 and over who have a confirmed allergy to egg and children aged between 2 -17 who required admission to ICU for severe egg allergy



QIVc can be given in any setting to those with a known egg allergy

Storage of all flu vaccines

Efficacy, safety and quality may be adversely affected if vaccines are not stored at the temperatures specified in the licence.

Flu vaccines must be stored in accordance with manufacturer's instructions:

store between +2ºC and +8ºC
do not freeze
store in original packaging
protect from light.

Check expiry dates regularly:

the LAIV has an expiry date 15 weeks after manufacture – this is much shorter than inactivated flu vaccines

always check the expiry date on before use.

Cold chain breach – please contact the duty room to report: 0300 555 0119 or pha.dutyroom@hscni.net.

Further resources (flu)

Comprehensive training slides for adult and childhood flu immunisation programmes* can be found at the following links:

- PHA Immunisation Training Slides - Tiles (hscni.net)
- Information for health professionals | HSC Public Health Agency (hscni.net)

Flu Immunisation training recommendations GOV.UK (www.gov.uk)

Flu patient information leaflets

Seasonal influenza (flu) surveillance | HSC Public Health Agency (hscni.net)

COVID-19 vaccine autumn 2024/25 (adult programme)

Spikevax JN.1 0.1mg/ml dispersion for injection





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Presentation and dose

- the vaccine packs contain 10 multidose vials of vaccine – (50 doses per box)
- a single dose is 0.5 ml
- if the dose-sparing needles and syringes are used, it should be possible to obtain at least 5 full 0.5ml doses from the vial
- the vaccine is contained in a multidose clear glass vial. The vial has a rubber (synthetic bromobutyl) stopper, aluminium seal and a **blue** flip-off plastic cap
- the vaccine **does not** require dilution
- for individuals who have previously been vaccinated, Spikevax® JN.1 should be administered at least 3 months after the most recent dose of a COVID-19 vaccine

Preparation

- check the appearance of the vaccine. It should be white to off-white and may contain white or translucent product-related particulates
- gently mix by swirling the vials prior to use. **Do not shake the vaccine vial**
- the vial bung should be wiped with an alcohol swab and allowed to air-dry fully
- do not use the vaccine if the time of first puncture was more than 6 hours previously
- withdraw a dose of 0.5 ml for each vaccination. **Take particular care to ensure the correct dose is drawn up as a partial dose may not provide protection**

Storage of thawed Spikevax®

- **thawed vaccine must be transferred immediately to a vaccine fridge on arrival and stored in a carefully monitored temperature range of +2ºC and +8ºC**

- once thawed, the unopened vaccine may be stored refrigerated at +2ºC to +8ºC, protected from light, for up to **30 days**

- the expiry date on the outer carton should have been updated to reflect the refrigerated (thawed) expiry date and the original expiry date should have been crossed out

- the unopened vaccine may be stored at 8°C to 25°C up to 24 hours after removal from refrigerated conditions

Contraindications to COVID-19 vaccines

- the COVID-19 Moderna (Spikevax) vaccines should not be given to people who have had a **confirmed anaphylactic reaction to the vaccine or any components of the vaccine**. Expert advice should be sought where either contraindication is present

- polyethylene glycol (PEG) is an allergen commonly found in medicines and also in household goods and cosmetics. Known allergy to PEG is extremely rare but would contraindicate receipt of Moderna (Spikevax) vaccines

- **the vast majority of people will not be at risk of anaphylaxis after being administered the COVID-19 vaccines**

Precautions to COVID-19 vaccines

Further advice on the management of individuals with a history of allergy can be found in the Green Book, chapter 14a, table 5:

Greenbook chapter 14a (publishing.service.gov.uk)

Table 5: Management of patients with a history of allergy

	Proceed with vaccination (no special precautions)	Special precautions	Vaccination contra-indicated
PATIENT CHARACTERISTICS	• previous allergic reaction (including anaphylaxis) to a food, insect sting and most medicines (where trigger has been identified) • previous non-systemic reaction to a vaccine • hypersensitivity to non-steroidal anti-inflammatory drugs e.g. aspirin, ibuprofen • mastocytosis	• prior non-anaphylaxis allergic reaction to COVID-19 vaccine • history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate PEG allergy) • history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (e.g. depot steroid injection, laxative) • history of idiopathic anaphylaxis	• prior anaphylaxis reaction to COVID-19 vaccine • prior systemic allergic reaction to a component of the vaccine (for known PEG allergy see text above)
ACTIONS	• proceed with vaccination in any setting • some individuals may be reassured by being observed for 15 minutes (may not be required if previously tolerated the same vaccine) • some patients (e.g. those with mastocytosis) may benefit from pretreatment with anti-histamine to reduce allergic symptoms	• consider possibility of PEG allergy and seek allergy advice if needed • a person has previously tolerated a dose of the same vaccine, it is safe to administer in any setting. Otherwise - consider giving vaccine and observe for 30 minutes	• refer to allergist or other appropriate specialist • consider administration of the implicated mRNA vaccine under medical supervision in hospital, or, where reaction was to a non-mRNA vaccine give alternative vaccine in any setting • consider observation for 30 minutes

Precautions to COVID-19 vaccines (continued)

- cases of myocarditis and pericarditis have been reported rarely after Spikevax® (Moderna COVID-19 vaccines)

- individuals who develop myocarditis or pericarditis following COVID-19 vaccination should be assessed by an appropriate clinician to determine whether it is likely to be vaccine related. subsequent doses should be deferred pending further investigation Information for healthcare professionals on myocarditis and pericarditis following COVID-19 vaccination - GOV.UK (www.gov.uk)

- a small number of cases of capillary leak syndrome have been reported after vaccination with Spikevax®, some of whom had a prior history of this condition

- individuals with a history of capillary leak syndrome, should be carefully counselled about the risks and benefits of vaccination and advice from a specialist should be sought

- having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the patient is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine

Co-administration (COVID and flu vaccines)

- no interval required between influenza and COVID-19 vaccines, or any other vaccine excepting RSV in older adults (see slides above)

- if the vaccines are not given together, they can be administered at any interval, although separating the vaccines by a day or two will avoid confusion over systemic side effects

- if two or more intramuscular vaccines are given at the same time, they should be given in separate sites (preferably a separate limb) and leave at least 2.5 cms between administration sites

- where possible, it is preferable that flu and COVID-19 vaccines are co-administered for eligible individuals in the autumn 2024/25 seasonal campaign

Pregnancy

- pregnant women should be offered the flu and COVID-19 vaccinations, as pregnancy has been identified as a clinical risk for serious illness from influenza and COVID-19
- there is no known risk associated with giving non-live vaccines during pregnancy. Since these vaccines cannot replicate, they cannot cause infection in either the woman or the unborn child
- data is more limited for LAIV
- there is no evidence of risk with LAIV. The live attenuated viruses cannot replicate efficiently elsewhere in the body and therefore there is no theoretical basis for concern about infection of the fetus or the mother
- inactivated influenza vaccines are, however, preferred for those who are pregnant
- routine questioning about last menstrual period and/or pregnancy testing is not required before offering flu or COVID-19 vaccines

Reporting adverse reactions

The inactivated quadrivalent flu vaccines (QIVc and aQIV), Spikevax ® and Abrysvo® carry a black triangle symbol (▼) as newly licensed vaccines in the UK and are subject to additional monitoring under the **black triangle** labelling scheme by the Medicines and Healthcare Regulatory Agency (MHRA). All suspected adverse reactions should be reported to the MHRA using the Yellow Card scheme.

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The QR code can be used for quick and easy access to the Yellow Card reporting site

Anyone (patients and health care workers) can make a Yellow Card report, even if they are uncertain as to whether a vaccine c
condition.



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Further resources (COVID-19 and general)

- COVID-19 Professional information | HSC Public Health Agency (hscni.net)
- COVID-19 training recommendations Training recommendations for COVID-19 vaccinators - GOV.UK (www.gov.uk)

General vaccination resources;

- E learning resources NHSE elfh Hub (e-lfh.org.uk)
- National Immunisation policy – the Green Book
- Guidance on vaccine handling and storage in GP practices