

# Frequently Asked Questions about COVID-19 vaccines for people with pre-existing allergic conditions

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## Frequently Asked Questions about COVID-19 vaccines for people with pre-existing allergic conditions

This follow-on brief document has been created to replace the original detailed FAQ developed to support the roll out of COVID-19 vaccines. Initial concerns about allergenicity of COVID-19 mRNA vaccines have not been supported by evidence. Since the COVID-19 vaccine campaign began in 2020, a great deal of knowledge has been gathered, and people with pre-existing allergic conditions can be safely vaccinated using the standard procedures in use in vaccination centres. Furthermore, concerns about the potential allergenicity of adjuvants in COVID-19 vaccines have not been supported by the majority of evidence. Adjuvant allergy remains extremely rare.

This document provides guidance regarding the following COVID-19 vaccines:

Vaccines in use currently	Vaccines used in the past
<b>mRNA vaccines</b>	<b>mRNA vaccines</b>
<i>Pfizer-BioNTech</i>	<i>Pfizer-BioNTech</i>
Comirnaty (3 micrograms)	Comirnaty (30 and 10 micrograms)
Comirnaty Original/Omicron BA.4-5 (30 and 10 micrograms)	Comirnaty Original/Omicron BA.1 (30 and 10 micrograms)
Comirnaty Omicron XBB.1.5 (30, 10 and 3 micrograms)	
	<i>Moderna</i>
	Spikevax (100 and 50 micrograms)
	Spikevax bivalent Original/Omicron BA.1 (50 micrograms)
	Spikevax bivalent Original/Omicron BA.4-5 (50 micrograms)
<b>Protein subunit vaccines</b>	<b>Protein subunit vaccines</b>
<i>Novavax</i>	<i>Novavax</i>
Nuvaxovid XBB.1.5 (5 micrograms)	Nuvaxovid (5 micrograms)
	<i>Sanofi GSK</i>
	VidPrevtyn Beta (5 micrograms)
	<b>Adenoviral vector vaccines</b>
	<i>Janssen</i>
	Jcovden (0.5ml)

This document relates only to questions about pre-existing allergic conditions that vaccinators might encounter during consent. Specific COVID-19 vaccine administration advice is covered in the Immunisation Guidelines for Ireland. This document is not a guide on how to treat anaphylaxis. All registered vaccinators have completed anaphylaxis training. For more information see the Anaphylaxis Section of the Immunisation Guidelines for Ireland.

## **Q1. How common is anaphylaxis after COVID-19 vaccines?**

**A.** Vaccine-associated anaphylaxis is very rare. However, any vaccine can cause anaphylaxis. The estimated rate for all vaccines, pre COVID-19, was 1.3 per million vaccine doses (1). Anaphylaxis after COVID-19 vaccination is now known to be much rarer than originally thought. In 2020 it was estimated to be 11.1 cases /million vaccine doses administered. Now the estimate is around 5/million (2). Analysis of UK data indicates that it is five times less frequent after booster doses compared with the first dose (3). It is also worth noting that the criteria applied retrospectively to defined cases of vaccine related anaphylaxis are prone to overestimation (4). Reassuringly, analysis of two pharmacovigilance databases reported a decreasing incidence of anaphylaxis following vaccination with COVID-19 vaccines between two time periods: (a) week 52 of 2020 and week 39 of 2021 and (b) week 52 of 2020 and week 1 or 2 of 2023 (5).

## **Q2. Can we predict who is going to have anaphylaxis following a COVID-19 vaccine?**

**A.** No. it remains unclear why people develop anaphylactic reactions to the COVID-19 vaccine.

The current contraindications to receiving a particular COVID-19 vaccine are:

- A history of anaphylaxis (systemic allergic reaction) following that COVID-19 vaccine.
- A history of anaphylaxis following another COVID-19 vaccine of the same platform e.g., mRNA or protein subunit vaccine.
- A history of anaphylaxis to any of the constituents of the vaccine being offered.
- A history of anaphylaxis to an alternative vaccine only if it contains a similar excipient, and that excipient has not been subsequently tolerated.

### Q3. What should I look for when asking a person about their report of previous anaphylaxis?

A. Anaphylaxis is a severe, life-threatening systemic allergic reaction characterised by rapid onset (usually within 15 minutes but up to 2 hours, rarely longer). If previous anaphylaxis is reported, vaccinators should check for the following typical features:

- **Two or more of the following after exposure to a likely allergen (e.g., food, insect sting, medication):**
  - Skin and/or mucosal tissue involvement (flushing, itch, urticaria rash/hives, swelling)
  - Difficulty breathing (wheeze, stridor, heavy chest / tightness)
  - Reduced blood pressure (BP) or suggestive symptoms (e.g., dizziness, visual loss)
  - Persistent severe gastrointestinal (GI) symptoms.
- **Reduced blood pressure (BP) after exposure to a known allergen.**
- **Acute onset of skin and or mucosal tissue involvement, airway compromise, reduced BP or associated symptoms, persistent severe GI symptoms, without an identifiable cause (unexplained or idiopathic anaphylaxis).**

Useful Link:

Differentiating vasovagal episodes and anaphylaxis ([Anaphylaxis Section, Table 1](#)).

#### Q4. What are the excipients in COVID-19 vaccines that have caused concern about anaphylactic reactions?

Potentially allergenic excipient	Anaphylaxis history that would suggest allergy to that excipient  The summary of product characteristics of any medication can be checked at <a href="https://www.medicines.ie/">https://www.medicines.ie/</a>	COVID-19 vaccines containing the excipient
<b>Polyethylene glycol (PEG)/ Macrogol</b>	<p>PEG allergy should be suspected in people reporting anaphylaxis after:</p> <ul style="list-style-type: none"> <li>• drinking oral laxative bowel preparations for colonoscopy procedures and laxatives such as Movicol, Mirilax, Dulcolax</li> <li>• steroid joint injections (methylprednisolone acetate - Depo-Medrone)</li> <li>• depot progesterone contraceptive (Depo-Provera)</li> <li>• Teedex</li> </ul> <p>People presenting with a history of anaphylaxis to multiple classes of drugs may also have PEG allergy</p>	<p>Comirnaty (30 micrograms (ready to use), 10 and 3 micrograms)</p> <p>Comirnaty Original/Omicron BA.1 (30 and 10 micrograms)</p> <p>Comirnaty Original/Omicron BA.4-5 (30 and 10 micrograms)</p> <p>Comirnaty Omicron XBB.1.5 (30, 10 and 3 micrograms)</p> <p>Spikevax (100 and 50 micrograms)</p> <p>Spikevax bivalent Original/Omicron BA.1 (50 micrograms)</p> <p>Spikevax bivalent Original/Omicron BA.4-5 (50 micrograms)</p>
<b>Trometamol</b>	Anaphylaxis to an MRI (gadolinium) dye (extremely rare)	<p>Comirnaty (30, 10 and 3 micrograms)</p> <p>Comirnaty Original/Omicron BA.1 (30 and 10 micrograms)</p> <p>Comirnaty Original/Omicron BA.4-5 (30 and 10 micrograms)</p> <p>Comirnaty Omicron XBB.1.5 (30, 10 and 3 micrograms)</p> <p>Spikevax (100 micrograms and 50 micrograms)</p> <p>Spikevax bivalent Original/Omicron BA.1 (50 micrograms)</p> <p>Spikevax bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)</p>

<b>Polysorbate (PS) 80</b>	<p>PS 80 allergy should be considered in the event of a recent history of anaphylaxis to vaccines including diphtheria, tetanus acellular pertussis, Hep B, HPV, and herpes zoster vaccines (Shingrix).</p> <p>Note most people who report vaccine reactions have had non-allergic reactions: redness at the site or feeling faint. These are not a contraindication to receiving a COVID-19 vaccine.</p> <p>History of anaphylaxis to injectable biological agents and monoclonal antibodies contain PS 80, including Rituximab and Infliximab.</p> <p>Recent ingestion of Vimovo or Nexium without adverse reaction would indicate PS80 tolerance</p>	<p>Jcovden (0.5ml)</p> <p>Nuvaxovid (5 micrograms)</p> <p>Nuvaxovid XBB.1.5 (5 micrograms)</p>
<b>Polysorbate (PS) 20</b>		VidPrevryn Beta (5 micrograms)

## **Q5. How do I establish whether a person, with a history of unexplained anaphylaxis, is not allergic to one of the COVID-19 vaccine components?**

**A.** Most cases of anaphylaxis can be explained by a detailed allergy focused history. A history will usually reveal if the anaphylaxis was related to food, medication, bee stings etc. In a case of unidentifiable medication related anaphylaxis, try to establish if the individual is tolerant to PEG and polysorbate by inquiring about other medications they may have taken, and check their SPC.

Idiopathic anaphylaxis is a term used when full immunological work up has not identified a cause. These people should be carrying adrenaline autoinjectors and wearing alert bracelets. This diagnosis is not a contraindication to receiving a COVID-19 vaccination.

## **Q6. Who should be considered for referral to the Allergy/Immunology team for review before receiving their COVID-19 vaccination?**

**A.** Consider referral of patients with a convincing history of anaphylaxis (see Q4) associated with:

- a. A previous COVID-19 vaccine
- b. PEG containing medication, unless review of medications indicates tolerance of PEG

- c. Polysorbate containing medication or vaccine, unless review of medications indicates tolerance of polysorbate.
- d. Multiple medications in different classes, unless review of medications indicates tolerance of PEG and polysorbate.

### **Q7. Can a person who has had an allergic reaction to the first dose of a COVID-19 vaccine receive a second dose?**

**A.** Yes, most people who have had an immediate reaction to the first dose of vaccine have had non-allergic reactions such as redness at the site, feeling faint etc. These are not allergic reactions. Anyone who has had mild allergic signs such as localised urticaria should receive their second dose as normal. Persons who have had confirmed anaphylaxis (see Q4) should be referred for evaluation (6).

### **Q8. What other conditions are neither contraindications nor precautions to COVID-19 vaccines?**

**A.** The following conditions are not a contraindication or a precaution to COVID-19 vaccines.

Persons with any of these conditions should be vaccinated as scheduled.

- a. All food allergic patients including those with a history of anaphylaxis
- b. Mild allergic reactions to vaccinations or previous local reactions to vaccines
- c. Family history of allergy, including anaphylaxis
- d. Asthmatics
- e. Those with an Allergy to antibiotics or NSAID
- f. Previous local reaction to any vaccine
- g. Mastocytosis and Mast cell activation syndrome
- h. Hereditary angioedema
- i. Contact dermatitis to PEG containing cosmetic product
- j. Chronic Spontaneous urticaria and angioedema and Physical/Inducible Urticarias
- k. Those with a history of allergic reactions to contrast dyes other than MRI dyes

## Q8. Are there any special allergic considerations for those aged 6 months-11 years?

**A.** Atopy (eczema, asthma, food allergy) is very common in this age group. None of these conditions are a contraindication to receiving COVID-19 vaccination. The paediatric formulations of Comirnaty contain trometamol and polysorbate. In the rare event that a child in this age group had a history consistent with anaphylaxis to gadolinium based MRI contrast media, they should have specialist allergy assessment, before proceeding with vaccination.

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