

Advice for the management of patients with reported allergies

Pfizer / BioNTech BNT162b2 vaccine

Contraindication

Hypersensitivity to the active substance or to any of the excipients listed below:

This vaccine contains polyethylene glycol/macrogol (PEG) as part of ALC-0159 – this belongs to a group of known allergens commonly found in medicines, cosmetics and household products.

- ALC-0315 = (4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate)
- ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide
- 1,2-Distearoyl-sn-glycero-3-phosphocholine
- cholesterol
- potassium chloride
- potassium dihydrogen phosphate
- sodium chloride
- disodium hydrogen phosphate dihydrate
- sucrose
- water for injections

This vaccine stopper is made from bromobutyl rubber and **DOES NOT** contain latex.

Cautions

Following close surveillance of the initial roll-out, the MHRA has advised that individuals with a history of anaphylaxis to food, an identified drug or vaccine, or an insect sting can receive any COVID-19 vaccine, as long as they are not known to be allergic to any component (excipient) of the vaccine. All recipients of the COVID-19 mRNA vaccine BNT162b2 should be kept for observation and monitored for a minimum of 15 minutes. Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8).

The British Society for Allergy and Clinical Immunology (BSACI) has advised that:

- Individuals with a history of immediate onset-anaphylaxis to multiple classes of drugs or an unexplained anaphylaxis should not be vaccinated with the Pfizer BioNTech vaccine. The AstraZeneca vaccine can be used as an alternative (if not otherwise contraindicated)
- Individuals with a localised urticarial (itchy) skin reaction (without systemic symptoms) to the first dose of a COVID-19 vaccine should receive the second dose of vaccine with prolonged observation (30 minutes) in a setting with full resuscitation facilities (such as a hospital)

- Individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to the first dose of a COVID-19 vaccine can receive the second dose of vaccine in any vaccination setting

Recommendations

All recipients of the COVID-19 mRNA vaccine BNT162b2 should be kept for observation and monitored for a minimum of 15 minutes. Facilities for management of anaphylaxis should be available at all vaccination sites.

Astra Zeneca / Oxford ChAdOx1-S vaccine

Contraindication

Hypersensitivity to the active substance or to any of the excipients listed below:

- L-Histidine
- L-Histidine hydrochloride monohydrate
- Magnesium chloride hexahydrate
- Polysorbate 80
- Ethanol
- Sucrose
- Sodium chloride
- Disodium edetate dihydrate
- Water for injections

This vaccine **DOES NOT** contain polyethylene glycol/macrogol (PEG)

This vaccine stopper is made from halobutyl rubber and **DOES NOT** contain latex.

Cautions

No specific cautions have been published regarding patients with a history of allergic reactions to other medicines, foods or insect stings.

Recommendations

There is no requirement for a 15 minute post-vaccination observation period, although this may be advisable for patients that report previous allergic reactions to other medicines, especially if the patient is to be driving away from the vaccination centre.

FREQUENTLY ASKED QUESTIONS

1) I am allergic to penicillin. Can I have a COVID-19 vaccination?

Yes, allergy to penicillins is not a contraindication to the Pfizer/BioNTech or AstraZeneca COVID-19 vaccine.

If you have a history of immediate onset anaphylaxis to *multiple classes of drugs* or *unexplained anaphylaxis* – see Questions 2&3.

2) I have had episodes of unexplained anaphylaxis. Are either of the COVID-19 vaccinations suitable for me?

The British Society for Allergy and Clinical Immunology (BSACI) has advised that:

‘Individuals with a history of immediate onset-anaphylaxis to multiple classes of drugs or an unexplained anaphylaxis should not be vaccinated with the Pfizer BioNTech vaccine. The AstraZeneca vaccine can be used as an alternative (if not otherwise contraindicated)’

This is because the Pfizer/BioNTech vaccine contains PEG and some people who have a history of unexplained anaphylaxis or of anaphylaxis to multiple classes of drugs could have an undiagnosed PEG allergy. Answers to these questions have been provided by members of the British Society for Allergy and Clinical Immunology. *Last updated 7th January 2021*

3) I have had anaphylaxis to many different medications in the past. Which vaccine should I be offered?

The British Society for Allergy and Clinical Immunology (BSACI) has advised that:

‘Individuals with a history of immediate onset-anaphylaxis to multiple classes of drugs or an unexplained anaphylaxis should not be vaccinated with the Pfizer BioNTech vaccine. The AstraZeneca vaccine can be used as an alternative (if not otherwise contraindicated)’

This is because the Pfizer/BioNTech vaccine contains PEG and some people who have a history of unexplained anaphylaxis or of anaphylaxis to multiple classes of drugs could have an undiagnosed PEG allergy.

4) I had some patches of itchy skin after my first dose of COVID-19 vaccination (but no systemic symptoms). Should I still get my second dose?

The British Society for Allergy and Clinical Immunology (BSACI) has advised that:

'Individuals with a localised urticarial (itchy) skin reaction (without systemic symptoms) to the first dose of a COVID-19 vaccine should receive the second dose of vaccine with prolonged observation (30 minutes) in a setting with full resuscitation facilities (e.g. a hospital)'

5) I have a latex allergy. Will the vaccine syringe contain latex?

No, according to the manufacturer, neither the Pfizer/BioNTech COVID-19 or AstraZeneca vaccine vial contains latex.

The Pfizer/BioNtech vaccination is supplied in vials that have a stopper made from Bromobutyl. This is a synthetic form of rubber which does not contain any dry natural rubber (latex). Pfizer have confirmed that latex is not used at all in the raw materials used to produce the vaccine.

The AstraZeneca vaccination is supplied in vials that have a stopper made from Halobutyl which is also a synthetic form of rubber which does not contain any dry natural rubber (latex)

It is important to let your Healthcare Provider know about your latex allergy so they can ensure they do not use any latex containing products whilst treating you.

6) I have a severe food allergy. Does this mean I am unable to have a COVID-19 vaccine?

The latest information in the Green Book Chapter 14a states :-

'Following close surveillance of the initial roll-out, the MHRA has advised that individuals with a history of anaphylaxis to food, an identified drug or vaccine, or an insect sting CAN receive any Answers to these questions have been provided by members of the British Society for Allergy and Clinical Immunology. *Last updated 7th January 2021*

COVID-19 vaccine, as long as they are not known to be allergic to any component (excipient) of the vaccine. All recipients of the Pfizer BioNTech COVID-19 vaccine should kept for observation and monitored for a minimum of 15 minutes. Facilities for management of anaphylaxis should be available at all vaccination sites.'

7) I have an egg allergy. Do the COVID-19 vaccines contain egg and are they safe to have?

Neither the Pfizer/BioNTech or the AstraZeneca COVID-19 vaccine contain any egg proteins and neither vaccine is contraindicated in egg allergy.

8) I am allergic to house dust mites. Can I have a COVID-19 vaccine?

Yes, allergy to aeroallergens such as house dust mites, pollen or animal allergens is not a contraindication to the Pfizer/BioNTech or the AstraZeneca COVID-19 vaccine.

9) What percentage of the population usually have a severe reaction to a vaccine?

The number of true allergic reaction to vaccines is very low. In the United Kingdom, only 1 case of anaphylaxis per million vaccine doses was reported between 1997 and 2003 (with no fatalities).

Many common side effects of vaccination such as localised pain and swelling at the site of injection or flu-like symptoms can be mistaken for allergy. They are not a reason to avoid the Pfizer/BioNTech or AstraZeneca COVID-19 vaccine.

10) Can patients who do not carry adrenaline and have had previous mild to moderate reactions to foods or drugs still have a COVID-19 vaccine?

Yes, there is no need to avoid the Pfizer/BioNTech COVID-19 or AstraZeneca vaccine if you have had a mild to moderate reaction to a food or an identified drug.

If you have a history of immediate onset anaphylaxis to *multiple classes of drugs* or *unexplained anaphylaxis* – see Questions 2&3.

11) Is there an increased risk for patients with asthma in having a COVID-19 vaccine?

No, there is not. However good asthma control in the weeks before vaccination is important (just like with all other vaccines). Answers to these questions have been provided by members of the British Society for Allergy and Clinical Immunology. *Last updated 7th January 2021*

12) Can individuals with a history of venom anaphylaxis have a COVID 19 vaccine?

Yes, allergy to venom is not a contraindication to the Pfizer/BioNTech or the AstraZeneca COVID-19 vaccine.

13) I have previously experienced immediate onset anaphylaxis to a food/medicine/vaccine. Can I have a COVID-19 vaccination?

The latest information in the Green Book Chapter 14a states :-

'Following close surveillance of the initial roll-out, the MHRA has advised that individuals with a history of anaphylaxis to food, an identified drug or vaccine, or an insect sting CAN receive any COVID-19 vaccine, as long as they are not known to be allergic to any component (excipient) of the vaccine. All recipients of the Pfizer BioNTech COVID-19 vaccine should be kept for observation and monitored for a minimum of 15 minutes. Facilities for management of anaphylaxis should be available at all vaccination sites.'

If you have a history of immediate onset anaphylaxis to *multiple classes of drugs* or *unexplained anaphylaxis* – see Questions 2&3.

14) I have Alpha-gal allergy and react to medicines containing gelatine. Is there any gelatine in the COVID-19 Vaccinations?

No. The ingredients for each vaccine are listed in the patient information sheet which you should be given to read prior to having your vaccination. There is no gelatine in the Pfizer/BioNTech or AstraZeneca vaccine.

15) I am allergic to all fish and have read that squalene, which comes from shark liver oil is used in some vaccines. Does the Pfizer/BioNTech contain squalene and does it pose a risk to me?

You are correct that squalene is used in some vaccines. It is highly purified fat that does not contain the proteins which cause the allergic reaction. It is not considered to pose any risk for patients with fish allergy.

Neither the Pfizer/BioNTech or AstraZeneca vaccination contain any squalene and there is no reason to suspect that they would cause any problems for someone allergic to fish. Answers to these questions have been provided by members of the British Society for Allergy and Clinical Immunology. *Last updated 7th January 2021*

16) I have a food allergy and carry adrenaline auto injectors. Should I bring them to my immunisation appointment just in case?

All people who carry adrenaline should take their two auto injectors with them everywhere they go. Anaphylaxis to a vaccine is extremely rare. Public Health guidelines require anyone responsible for giving a vaccine to receive training on the management of anaphylaxis.

A protocol for the management of anaphylaxis and an anaphylaxis pack which includes adrenaline must always be available whenever vaccines are given.

17) With other new COVID-19 vaccines in development, is there any reason to wait for a different vaccine? Will the other vaccines be suitable for people with allergies?

There are many COVID-19 vaccines in development with several in the final stages of trials and likely to become available over the coming months. Each vaccine is different, and they use a variety of different technologies. Until a vaccine is approved, we will not know exactly what the ingredients are, so it is impossible to comment on their safety or otherwise for people with particular allergies.

Before having any vaccination, it is important that you are given the patient information leaflet to read. This contains vital information about who should receive the vaccine along with a complete list of ingredients.