**FAQ For Housebound Patients Receiving AstraZeneca Vaccine**

**My patient has various allergies, can they have the AZ vaccine in a community setting?**

If your patient has an allergy or had an allergic reaction in the past and are on the clinically extremely vulnerable (CEV) list, under the care of a specialist who has agreed they can go ahead with vaccination, then please check the excipients for the AZ vaccine to see if the below criteria apply to them. If after checking individual excipients list for the AZ vaccine, there does not appear to be any currently known reason not to go ahead with AZ, then your patient may be vaccinated in the community setting.

**TABLE OF POTENTIAL ALLERGENS THAT MAY CAUSE ANAPHYLAXIS/ ALLERGIC REACTIONS – ASTRAZENECA® OXFORD VACCINE**

* **Antibiotics -** Individuals with previous allergy to an identified drug, including anaphylaxis, can receive the AstraZeneca COVID-19 vaccine.
* **Excipients** - A hypersensitivity to any of the excipients is a contraindication to the vaccine use. Excipientslisted in the [manufacturer’s information](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca) are as follows:
* L-Histidine
* L-Histidine hydrochloride monohydrate
* Magnesium chloride hexahydrate
* Polysorbate 80
* Ethanol
* Sucrose
* Sodium chloride
* Disodium edetate dihydrate
* Water for injections

The vaccine contains less than 1 mmol sodium (23 mg) per dose, it is essentially ‘sodium-free’.

* **Food** - Individuals with previous allergy to food, including anaphylaxis, can receive the AstraZeneca COVID-19 vaccine.

**Egg content** - The [manufacturer](https://d27mnwjqm5ztsa.cloudfront.net/4d4d150a-bf20-4c76-945a-ce2a670c3c99/609fc7da-06a7-45e4-b3cb-d9b05e3f1e60/609fc7da-06a7-45e4-b3cb-d9b05e3f1e60_viewable_rendition__v.pdf) states that the vaccine does not contain eggs. However, AstraZeneca does not manufacture the raw materials used in its products, and the suppliers may periodically change. Lack of contact with other ingredients during the manufacturing process cannot be guaranteed.

## Gluten - The [manufacturer](https://d27mnwjqm5ztsa.cloudfront.net/4d4d150a-bf20-4c76-945a-ce2a670c3c99/609fc7da-06a7-45e4-b3cb-d9b05e3f1e60/609fc7da-06a7-45e4-b3cb-d9b05e3f1e60_viewable_rendition__v.pdf) states that the vaccine does not contain any gluten. However, AstraZeneca does not manufacture the raw materials used in its products, and the suppliers may periodically change. Lack of contact with other ingredients during the manufacturing process cannot be guaranteed.

## Gelatin - The manufacturer states that the vaccine does not contain gelatin. However, AstraZeneca does not manufacture the raw materials used in its products, and the suppliers may periodically change. Lack of contact with other ingredients during the manufacturing process cannot be guaranteed.

## Nut content - The manufacturer states that the vaccine does not contain any peanut or tree nut derivatives. However, AstraZeneca does not manufacture the raw materials used in its products, and the suppliers may periodically change. Lack of contact with other ingredients during the manufacturing process cannot be guaranteed.

## Soy content - The manufacturer states that the vaccine does not contain any soy. However, AstraZeneca does not manufacture the raw materials used in its products, and the suppliers may periodically change. Lack of contact with other ingredients during the manufacturing process cannot be guaranteed.

* **Latex** -The vaccine can be considered not to contain latex and poses the same minimal risk as other injectable medicines presented in vials with a halobutyl rubber stopper.

[**Public Health England’s COVID-19 Vaccination Programme Information for Healthcare Professionals**](https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners)advice that the rubber stopper of each multidose vial of AstraZeneca vaccine consists of halobutyl, and does not contain latex.

Information in[**The Green Book (chapter 6)**](https://www.gov.uk/government/publications/contraindications-and-special-considerations-the-green-book-chapter-6)**,** which includes advice on managing vaccine choice in patients with severe (i.e. anaphylactic) allergy to latex, would categorise the AstraZeneca vaccine as not containing latex.

However, even if the components of an injection do not contain latex, or latex is not used as a raw material during manufacturing, most manufacturers of injectable products advise they cannot guarantee minute amounts of latex are not contained in raw materials obtained from their suppliers or the product has not come into contact with latex during the manufacturing process.

* **Other drugs** **-** Individuals with previous allergy to an identified drug, including anaphylaxis, can receive the AstraZeneca COVID-19 vaccine.
* **Polyethylene glycol (PEG) and Polysorbate 80** - PEG is not present in the AstraZeneca COVID-19 vaccine.

[Public Health England’s Immunisation Against Infectious Disease (the Green Book)](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) advises that the AstraZeneca vaccine may be used as an alternative in people with a PEG allergy.

The AstraZeneca COVID-19 vaccine contains polysorbate 80, according to the [Information for Healthcare Professionals](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca). The British Society for Allergy and Clinical Immunology (BSACI) advise in their [COVID-19 Vaccinations and Allergies FAQ](https://www.bsaci.org/wp-content/uploads/2021/01/v3Jan-2021-COVID19-Vaccines-and-Allergy-FAQ.pdf) that polysorbate 80 is found in many vaccines including the influenza vaccine; they state that although polysorbate 80 is quite similar in structure to PEG, there are no reports of PEG-allergic patients reacting to it e.g. when receiving other vaccines and therefore the AstraZeneca COVID-19 vaccine is recommended as a suitable alternative.

[Public Health England’s Immunisation Against Infectious Disease (the Green Book)](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) also states that whether PEG is the cause of reactions in patients with systemic allergic symptoms after the first dose of Pfizer-BioNTech vaccine is unclear; patients with systemic allergic symptoms after the first dose of the Pfizer-BioNTech vaccine may be considered for a second dose using the AstraZeneca vaccine, and should be observed for 30 minutes following vaccination.

* **“Sulfa” medicines** - The [**Information for Healthcare Professionals**](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca) does not indicate that any “sulfa” medicines are present in the AstraZeneca COVID 19 vaccine.

## Thiomersal content - Suitability for vaccination is unlikely to be affected for individuals avoiding thiomersal. The [manufacturer](https://d27mnwjqm5ztsa.cloudfront.net/4d4d150a-bf20-4c76-945a-ce2a670c3c99/609fc7da-06a7-45e4-b3cb-d9b05e3f1e60/609fc7da-06a7-45e4-b3cb-d9b05e3f1e60_viewable_rendition__v.pdf) states that this vaccine does not contain any preservatives, thiomersal or any mercury derived product.

## Animal or human derived content - The [manufacturer](https://d27mnwjqm5ztsa.cloudfront.net/4d4d150a-bf20-4c76-945a-ce2a670c3c99/609fc7da-06a7-45e4-b3cb-d9b05e3f1e60/609fc7da-06a7-45e4-b3cb-d9b05e3f1e60_viewable_rendition__v.pdf) states that the vaccine is produced in a human cell line. These cells are lysed to release the vaccine and the cell debris is filtered during vaccine production. The [manufacturer](https://d27mnwjqm5ztsa.cloudfront.net/4d4d150a-bf20-4c76-945a-ce2a670c3c99/609fc7da-06a7-45e4-b3cb-d9b05e3f1e60/609fc7da-06a7-45e4-b3cb-d9b05e3f1e60_viewable_rendition__v.pdf) states that the final vaccine product does not contain human-derived cells.

## Halal certification - There is no information on Halal certification for the AstraZeneca vaccine. However, the [British Islamic Medical Association has released a position statement](https://britishima.org/covid19-vaccine-az/).

## Jewish community - The [Conference of European Rabbis has released a position statement](https://rabbiscer.org/wp-content/uploads/2020/12/CER-Vaccination-.pdf).

**Please can you clarify timing of the second dose?**

NHSE wrote to primary care healthcare staff on January 7th setting out clear instructions on offering second dose vaccinations to ensure maximum optimisation of the vaccination programme.

Due to a rapid increase in cases in December and January, resulting in a large increase in hospitalisations and the emergence of a new variant, it is imperative we step up the pace of vaccination.

Updated guidance from the independent JCVI and the UK chief medical officers was published on 30 December. It sets out the need to increase spacing of second doses for the AstraZeneca vaccine:

Vaccinating twice the number of people in the next 2-3 months is preferable in public health terms to vaccinating half the number with only slightly greater individual protection. This public health approach is centred on doing as much good for as many people as possible in the shortest possible time which means all patient’s should be booked in for a second dose in the 12th week.

The short-term vaccine efficacy from the first dose of the Oxford AstraZeneca is around 70%, with high protection against severe disease.

**Is it acceptable to move the AZ vaccine between housebound patient’s homes once the vial has been punctured?**

NHSE advises that there are no concerns from a movement stability perspective of transporting the AZ vaccine from house to house to support vaccination of housebound patients.

The vaccine should be stored at +2 to 8°C until first use. If it is moved during this period, the cold chain must be assured and maintained. After the vial has been punctured, the vaccine should be used as soon as practically possible and within 6 hours. Once punctured the 6-hour expiry must be recorded on the vial. The vaccine may be stored between 2°C and 25°C during the in-use period.

The **SPS SOP AVH7 Transporting AZ Covid-19 Vaccine** outlines best practice for transporting vaccine from home to home. It recommends transporting the vaccine in a validated cool box to limit the risk of microbiological contamination of an unpreserved vaccine and segregation of punctured and un-punctured vials.

**Can vaccines be moved between care homes?**

The movement of punctured vials of AstraZeneca COVID-19 vaccine between multiple sites presents a greater risk of microbiological contamination. There is a need to protect vaccine quality, minimise the risk of harm to the patient from accidentally administering contaminated vaccine and minimise vaccine wastage. Practices are advised that moving a punctured vial of the AstraZeneca vaccine between care homes should only occur in rare circumstances, for example when it is essential to vaccinate a small number of patients in each of several care homes as part of a “mop up” exercise within a 6 hour period to avoid significant wastage.

**Can I vaccinate a patient who has rhinitis and is on inhaled steroids and antibiotics?**

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. 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 (including COVID-19) by wrongly attributing any signs or symptoms to the adverse effects of the vaccine.

**Can Covid-19 vaccine can be given to those on anticoagulants?**

The Green Book advises that individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual’s bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/ treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/ treatment is administered***.***

***Individuals on stable anticoagulation therapy, including individuals on warfarin who are up-to-date with their scheduled INR testing and whose latest INR is below the upper level of the therapeutic range, can receive intramuscular vaccination.***

The individual/parent/ carer should be informed about the risk of haematoma from the injection.

**Additionally Region (NHSE & I) has issued a Position Statement: Covid 19 vaccine and patients prescribed anticoagulants. They recommend:**

* Individuals receiving direct oral anticoagulant (apixaban, dabigatran, edoxaban & rivaroxaban) or warfarin in therapeutic INR range or on full dose heparin or fondaparinux injections can all receive the COVID 19 vaccination
* There is an increased risk of bruising at the injection site but we do not anticipate any serious effects related to anticoagulation
* that after the injection prolonged pressure (at least 5 minutes) should be applied to the injection site to reduce bruising
* Patients on warfarin with supra therapeutic INR should wait until their INR is <4.0
* Encourage patients to have vaccinations and they should not be avoided on the basis of being on anticoagulation
* Patients with inherited bleeding disorders such as Haemophilia need to seek advice from their own Haemophilia Centre to ensure they receive the vaccine safely

**Key Points**

The COVID vaccines, whilst novel, are not themselves contraindicated for patients on anticoagulation. The key risk assessment is from the use of intramuscular injection. Patients on anticoagulation are generally advised to avoid intramuscular injection due to the risk of haematoma formation due to tissue injury and puncture of small blood vessels by the needle used to vaccinate, however:

1. There are a number of studies which have documented the relative risk of injections in anticoagulated patients.

2. We also know that warfarin does not need to be discontinued for a number of invasive procedures such as dental procedures and endoscopy with submucosal biopsy, and arthroscopy.

3. PGDs for flu vaccination, recommend patients on anticoagulation within a therapeutic dose can receive intra muscular influenza vaccination with sufficient pressure applied for a sufficient period of time to ensure there is no leakage of blood into muscle tissue.

**Can the covid-19 vaccine be given at the same time as the flu vaccine?**

Regarding the co-administration of the flu and COVID-19 vaccines, there is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult.

The **green book** advises that there should ideally be an interval of at least 7 days between the two to avoid incorrect attribution of potential adverse events. However, if this is not possible, then it is acceptable to give both together “as both of the early COVID-19 vaccines are considered inactivated (including the non-replicating adenovirus vaccine), where individuals in an eligible cohort present having received another inactivated or live vaccine, COVID-19 vaccination should still be considered.”

This is to avoid any further delay in protection and to avoid the risk of the patient not returning for a later appointment.

**How to Report Side Effects to the vaccine?**

All healthcare professionals should be aware of the process for reporting any COVID19 vaccine-related side effects reported to them by their patients.

Practices who are not directly currently involved in vaccinations may still be approached by their patients with information regarding side effects. It is very important that this information is captured both in the patients’ own records and in national reporting schemes.

Please note that this **includes all clinical adverse events** that occur after administration of the COVID19 vaccine.

For all clinical adverse events, **two reporting actions are required**:

* report to the MHRA Yellow Card scheme **and**
* a report to the RVOC on **england.london-covid19voc@nhs.net**

Practices should include Mary Clarke (GP Confederation Clinical Lead **mary.clarke13@nhs.net**) in correspondence regarding side effects to reduce potential duplication of reporting.

**What about Covid vaccine and fertility?**

Royal College of Obstetricians and Gynaecologists have published **information and advice for pregnant women about the COVID-19 vaccine,** including an updated Q&A section. The College also released a **press notice,** responding to misinformation around the COVID-19 vaccine and fertility.

Recent advice from the MHRA on the COVID-19 vaccines authorised for use in the UK, including advice for people with allergies and for women during pregnancy and breastfeeding - <https://www.gov.uk/drug-safety-update/covid-19-vaccines-pfizer-slash-biontech-and-covid-19-vaccine-astrazeneca-current-advice>

For further information about the COVID-19 vaccines please refer to [Public Health England’s Immunisation Against Infectious Disease (the Green book)](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a).

[Chapter 1 of Public Health England’s Immunisation Against Infectious Disease (the Green book)](https://www.gov.uk/government/publications/immunity-and-how-vaccines-work-the-green-book-chapter-1) also contains a section on ‘How are vaccines made’ (page 4).