IMPORTANT: This document provides a quick reference of the vaccine characteristics and excipients information for the three COVID-19 vaccines currently available through the UK COVID-19 vaccination programme. The information in this document is correct as of the date of writing on 12/1/2021.

Characteristics	Pfizer/BioNTech	Oxford University/AstraZeneca	Moderna		
Therapeutic indication	For active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16	For active immunisation to prevent COVID-19 in individuals 18 years of age and over.	For active immunisation to prevent COVID-19 caused by the SARS-CoV-2 virus, in individuals		
	years of age and over.		18 years of age and older.		
Type of vaccine	Messenger RNA (mRNA) vaccine BNT162b2 concentrate for solution for injection.	Adenovirus vector.	Messenger RNA (mRNA) vaccine (nucleoside modified).		
Composition	Multidose vial which must be diluted before use. One vial (0.45ml) contains 5 doses of 30 micrograms of BNT162b2 RNA.	One dose (0.5 ml) contains COVID-19 vaccine (ChAdOx1-Srecombinant) 5 × 10 ¹⁰ viral particles.	Multidose vial with one vial containing 10 doses. One dose (0.5 mL) contains 0.10 mg of mRNA (embedded in lipid nanoparticles).		
Pharmaceutical form	Concentrate for solution for injection.	Solution for injection.	Dispersion for injection.		
Colour	White to off-white frozen solution.	Colourless to slightly brown, clear to slightly opaque and particle free.	White to off-white frozen dispersion (pH: 7.0 – 8.0).		
Dosage schedule	Two doses (0.3mL each) with an interval of between 3 to 12 weeks.	Two doses (0.5mL each) with an interval of between 4 and 12 weeks	Two doses (0.5 mL each). It is recommended to administer the second dose 28 days after the first dose.		
Method of	Intramuscularly into the deltoid muscle after	Intramuscular injection only, preferably in the	Intramuscular injection only, preferably in the		
administration	dilution.	deltoid muscle.	deltoid muscle.		
Contraindication	Hypersensitivity to the active substance or to any of the excipients listed.	Hypersensitivity to the active substance or to any of the excipients listed.	Hypersensitivity to the active substance or to any of the excipients listed.		
Special warnings	Hypersensitivity and anaphylaxis: events	Hypersensitivity: appropriate medical	Anaphylaxis: Events of anaphylaxis have		
and precautions	of anaphylaxis have been reported.	treatment and supervision should always	been reported. Appropriate medical		
	Appropriate medical treatment and	be readily available in case of an	treatment and supervision to manage		
	supervision should always be readily	anaphylactic event following the	immediate allergic reactions must always		
	available in case of an anaphylactic reaction	 administration of the vaccine. Concurrent illness: administration should 	be readily available in case of an acute		
	following the administration of the vaccine. Close observation for at least 15 minutes is	 Concurrent illness: administration should be postponed in individuals suffering from 	anaphylactic reaction following administration of the vaccine. Close		
	recommended following vaccination. A	an acute severe febrile illness. However,	observation for at least 15 minutes is		
	second dose should not be given to those	the presence of a minor infection, such as	recommended following vaccination.		

Table 1: characteristics of the Pfizer/BioNTech, Oxford University/AstraZeneca and Moderna vaccines

© The National Pharmacy Association. January 2021. Produced by the Pharmacy Services team. **Direct Dial:** 01727 891 800 **Email:** <u>pharmacyservices@npa.co.uk</u> **Online:** <u>www.npa.co.uk</u>



who have experienced anaphylaxis to the first dose.

On 9 December 2020, the <u>MHRA advised</u> any person with a history of immediateonset anaphylaxis to a vaccine, medicine or food should not receive the vaccine. On 30 December 2020, the <u>CHM recommended</u> that, following a review of further data, any person with a previous history of allergic reactions to the excipients of the vaccine should not receive it; however, those with any other allergies, such as a food allergy, can now have the vaccine. Please see the <u>PHE guidance: "Information for healthcare</u> practitioner" for more detail.

- **Traceability**: in order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.
- Acute severe febrile illness: the vaccine should be postponed in individuals suffering from acute severe febrile illness.
- Anticoagulant therapy and bleeding disorders: individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection, should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration. Please refer to the PHE <u>"COVID-19 vaccination programme</u> <u>guidance for healthcare practitioners"</u> for more details.

cold, and/or low-grade fever should not delay vaccination.

- **Traceability:** in order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.
- Thrombocytopenia and coagulation disorders: should be given with caution to individuals with thrombocytopenia, any coagulation disorder or to persons on anticoagulation therapy, because bleeding or bruising may occur following an intramuscular administration in these individuals.
- Immunocompromised individuals: it is not known whether individuals with impaired immune responsiveness, including individuals receiving immunosuppressant therapy, will elicit the same response as immunocompetent individuals to the vaccine regimen.

- **Traceability**: in order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.
- Anxiety-related reactions: including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting.
- Immunocompromised individuals: the efficacy, safety and immunogenicity have not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of vaccine may be less in these individuals.
- **Coagulation disorders**: should be given with caution in individuals with bleeding disorders, such as haemophilia, or individuals currently on anticoagulant therapy, to avoid the risk of haematoma following the injection.
- Acute illness: immunisation should be postponed in individuals with severe febrile illness or severe acute infection. Individuals with moderate or severe acute illness should be vaccinated as soon as the acute illness has improved.



© The National Pharmacy Association. January 2021. Produced by the Pharmacy Services team. **Direct Dial:** 01727 891 800 **Email:** <u>pharmacyservices@npa.co.uk</u> **Online:** <u>www.npa.co.uk</u>

	•	Immunocompromised individuals:				
		including individuals receiving				
		immunosuppressant therapy, may have a				
		diminished immune response to the				
		vaccine. No data are available about				
		concomitant use of immunosuppressants.				
Interactions with	•	No interaction studies have been	•	No interaction studies have been	•	No interaction studies have been
other medicinal		performed including concomitant		performed including concomitant		performed including concomitant
products		administration with other vaccines.		administration with other vaccines.		administration with other vaccines.
	•	Do not mix with other vaccines/products in				
		the same syringe.				
Shelf life and	•	Store in a freezer at -80°C to -60°C shelf life	•	Unopened multidose vial: 6 months in a	•	Store at -25°C to -15°C shelf life of 7
special		6 months. Store in the thermal container at		refrigerator (2°C to 8°C). Do not freeze.		months. Do not store or transport on dry
precautions for		-90°C to -60°C.		Keep vials in outer carton to protect from		ice or below -40°C. Protect from light.
storage	•	Store in the original package in order to		light.	•	After thawing, the vaccine should not be
		protect from light.	•	After first use: use as soon as practically		re-frozen and may be stored refrigerated at
	•	Once removed from the freezer, the		possible and within 6 hours. The vaccine		2°C to 8°C protected from light for up to 30
		undiluted vaccine can be stored for up to 5		may be stored between 2°C and 25°C		days if not used (needle-punctured).
		days at 2°C to 8°C, and up to 2 hours at		during the in-use period.	•	Chemical and physical stability of an
		temperatures up to 25°C, prior to use.				unopened vial after removal from
	•	During storage, minimise exposure to room				refrigerated conditions has been
		light, and avoid exposure to direct sunlight				demonstrated for 12 hours at 8° to 25°C.
		and ultraviolet light.				Do not refreeze.
	•	Thawed vials can be handled in room light			•	Punctured vial: Chemical and physical in-
		conditions.				use stability has been demonstrated for 6
	•	After dilution, store the vaccine at 2°C to				hours at 2°C to 25°C after first puncture.
		25°C and use as soon as practically possible				From a microbiological point of view, the
		and within 6 hours.				product should be used immediately. If not
	•	Once diluted, the vials should be marked				used immediately, in-use storage times and
		with the dilution time and discarded within				conditions are the responsibility of the
		6 hours of dilution.				user.
	•	Once thawed, the vaccine cannot be re-				
		frozen.				



Nature and	Concentrate for solution for injection for 5	5 ml of solution in a 10-dose vial or 4 ml of	Each vial contains a maximum of 10 doses of
contents of	doses in a 2 mL clear vial.	solution in an 8-dose vial vials. Pack size of 10	0.5 mL each. Pack size of 10 vials.
container	Pack size of 195 vials.	vials. Not all pack sizes may be marketed.	
Suitability in paediatrics	Safety and efficacy not established yet in children under 16 years of age.	Safety and efficacy not established in children under 18 years of age.	Safety and efficacy not yet established in children and adolescents less than 18 years of age.
Suitability in pregnancy	 There is limited data of the vaccine in pregnant women. Administration should only be considered when the potential benefits outweigh any potential risks. The Joint Committee on Vaccination and Immunisation (JCVI) has recognised that the potential benefits of vaccination are particularly important for some pregnant women. This includes those who are at very high risk of catching the infection or those with clinical conditions that put them at high risk of suffering serious complications from COVID-19. 	 There is a limited experience in pregnant women. Administration in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus. 	 There is limited experience in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development. Administration in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.
Suitable in	It is unknown whether it is excreted in human	It is unknown whether it is excreted in human	It is unknown whether it is excreted in human
breastfeeding	milk.	milk.	milk.
Effects on fertility	Animal studies do not indicate direct or indirect harmful effects with respect to fertility	Preliminary animal studies do not indicate direct or indirect harmful effects with respect to fertility.	Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.
Alcohol content	Ethanol is used in the manufacturing process and is then removed down to trace levels. Therefore, it is not listed in the final product composition	A very small amount of alcohol (0.002 mg of alcohol (ethanol) per dose of 0.5 ml). This is not enough to cause any noticeable effects.	Awaiting confirmation
Interchangeability	Individuals who have received one dose of COVID-19 mRNA Vaccine BNT162b2 should receive a second dose of COVID-19 mRNA Vaccine BNT162b2 to complete the vaccination series	Individuals who receive a first dose of COVID-19 Vaccine AstraZeneca should receive a second dose of COVID-19 Vaccine AstraZeneca to complete the vaccination series	Individuals who have received one dose of COVID-19 Vaccine Moderna should receive a second dose of COVID-19 Vaccine Moderna to complete the vaccination series.

© The National Pharmacy Association. January 2021. Produced by the Pharmacy Services team. **Direct Dial:** 01727 891 800 **Email:** <u>pharmacyservices@npa.co.uk</u> **Online:** <u>www.npa.co.uk</u>



Vaccine	Antibiotic free	Preservative free	Sodium free	Gluten free	Nut free	Soy free	Egg free	Vegetarian and vegan suitability	Halal certification
Pfizer/ BioNTech	\mathbf{x}^{1}	\checkmark	√2	√3	\checkmark^4	√5	√6	√7	× ⁸
Oxford University/ AstraZeneca	Awaiting confirmation	\checkmark	√ ⁹	√ 10	√11	√12	√ ¹³	√14	Awaiting confirmation
Moderna	Awaiting confirmation	\checkmark	√ ¹⁵	Awaiting confirmation	Awaiting confirmation	Awaiting confirmation	Awaiting confirmation	Awaiting confirmation	Awaiting confirmation

Table 2: Excipient information of the Pfizer/BioNTech and Oxford University/AstraZeneca vaccines

Кеу

¹*Pfizer* confirms Kanamycin is used during the manufacturing process; however, it is not expected to be in detectable quantities in the final product presentation. No other antibiotics (such as penicillins, sulphonamides and neomycin) are used during the manufacturing process. Pfizer cannot guarantee that minute amounts of substances are not contained in raw materials obtained from our suppliers. To ensure Pfizer has a consistent and reliable supply of medications, Pfizer must use a network of suppliers and manufacturing sites globally for both active and inactive ingredients

² *Pfizer* confirms less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

³ Pfizer confirms gluten is not used during the manufacturing of the vaccine and the final product does not contain gluten; however, Pfizer cannot guarantee that minute amounts of substances, such as gluten, are not contained in raw materials from their suppliers.

⁴ *Pfizer* confirms nuts are not used during the manufacturing of the vaccine and the final product does not contain nuts; however, Pfizer cannot guarantee that minute amounts of substances, such as nuts, are not contained in raw materials from their suppliers.

⁵ *Pfizer* confirms soy is not used during the manufacturing of the vaccine and the final product does not contain soy; however, *Pfizer* cannot guarantee that minute amounts of substances, such as soy, are not contained in raw materials from their suppliers.

⁶ *Pfizer* confirms eggs are not used during the manufacturing of the vaccine and the final product does not contain eggs; however, Pfizer cannot guarantee that minute amounts of substances, such as eggs, are not contained in raw materials from their suppliers.

⁷ *Pfizer* confirms a material used in the early stage of the manufacturing process of COVID-19 mRNA Vaccine BNT162b2 contains a component that is derived from bovine milk. The bovine milk is fit for human consumption and complies with bovine spongiform encephalopathy (BSE)/transmissible spongiform encephalopathies (TSE) regulations. Other raw materials used in the manufacture of the vaccine are of non-animal origin. All lipid excipients used in the vaccine are either from plant-derived sources or are synthetic and have no animal components. Pfizer cannot guarantee that minute amounts of substances are not contained in raw materials obtained from their suppliers.

⁸ Pfizer states that the vaccine was not submitted for halal certification prior to authorisation approval and they are currently investigating the submission/application process.

⁹ AstraZeneca confirms the vaccine contains less than 1 mmol sodium (23 mg) per dose, which means it is essentially 'sodium-free'.

¹⁰ AstraZeneca confirms the vaccine does not contain 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.

¹¹ AstraZeneca confirms the vaccine does not contain 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.



¹² AstraZeneca confirms the vaccine does not contain 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.

¹³ AstraZeneca confirms the vaccine does not contain egg; 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.

¹⁴ AstraZeneca confirms the vaccine does not contain any animal-derived products and excipients are of vegetable origin.

¹⁵ Moderna confirms less than 1 mmol sodium (23 mg) per 0.5ml dose, and is essentially 'sodium-free'.

References and further reading

- MHRA 'Pfizer/BioNTech COVID-19 vaccine': <u>https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19</u>
- MHRA 'AstraZeneca COVID-19 vaccine': <u>https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca</u>
- MHRA 'Moderna COVID-19 vaccine': https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna
- PHE 'COVID-19 vaccination guidance for healthcare practitioners': <u>https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners</u>
- MHRA 'Managing allergic reactions with Pfizer/BioNTech vaccine': <u>https://www.gov.uk/government/news/confirmation-of-guidance-to-vaccination-centres-on-managing-allergic-reactions-following-covid-19-vaccination-with-the-pfizer-biontech-vaccine</u>
- PHE 'A guide for women of childbearing age, pregnant or breastfeeding' : <u>https://www.gov.uk/governhhment/publications/covid-19-vaccination-women-of-childbearing-age-currently-pregnant-planning-a-pregnancy-or-breastfeeding/covid-19-vaccination-a-guide-for-women-of-childbearing-age-pregnant-planning-a-pregnancy-or-breastfeeding</u>
- SPS 'COVID-19 vaccines': https://www.sps.nhs.uk/home/covid-19-vaccines/

Disclaimer: The information published is, to the best of our knowledge, correct at the time of writing. However, no responsibility will be accepted by the NPA for any consequences of decisions made using this information.

