

AstraZeneca / Oxford Covid-19 Vaccine PATIENT INFORMATION LEAFLET

This leaflet should be used alongside the UKMFA general Covid-19 Vaccines Patient Information Leaflet¹

The MHRA provided authorisation for emergency supply of Covid-19 Vaccine AstraZeneca (AZD1222) in December 2020². At the time of writing, the safety and efficacy trials are set to conclude in February 2023. Recipients should be aware that this will remain an experimental vaccine at least until this time³. This leaflet provides further information for patients to consider before receiving the vaccine.

OVERVIEW

Vaccine type: Non-replicating, recombinant viral vector vaccine (also termed ChAdOx1 nCoV-19 and AZD1222).

How does it work? This vaccine uses a chimpanzee adenovirus as a vector to deliver a SARS-CoV-2 virus gene into the cells of the recipient's body. The SARS-CoV-2 virus gene (synthetic DNA) that encodes the virus spike protein is inserted into the adenovirus.⁴ Following injection of the vaccine, the adenovirus invades the recipient's cells and the viral gene is expressed by the host cell's machinery which starts to produce spike proteins. These proteins enter the bloodstream and the body mounts an immune response, creating antibodies.

Ingredients: Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS CoV 2 Spike (S) glycoprotein - produced in genetically modified

human embryonic kidney (HEK) 293 cells. This product contains genetically modified organisms (GMOs)⁵
Excipients: L-histidine, L-histidine hydrochloride monohydrate, magnesium chloride hexahydrate, polysorbate 80 (E 433), ethanol, sucrose, sodium chloride, disodium edetate dihydrate, water for injections⁶

What do we know about immunity from the vaccine?

- The vaccine is not believed to prevent viral transmission
- It is unknown how someone who has already had COVID-19 will react to the vaccine, as anyone with prior exposure was excluded from the trial
- The potential issue of pathogenic priming/antibody-dependent enhancement has not been ruled out (see UKMFA general Covid-19 vaccine leaflet for more info)
- "None of the trials currently underway are designed to detect a reduction in any serious outcome such as hospitalisations, intensive care use or deaths." stated Peter Doshi, British Medical Journal⁷
- It has not yet been approved for use under an EUA (emergency use authorisation) in the USA
- In May 2021, the JCVI recommended restricting its use to the over-40's in the UK⁸

¹
https://uploads-ssl.webflow.com/5fa5866942937a4d73918723/5fdcb8da3e69e028e9fd95e8_UKMFA_COVID-19_Vaccine_Patient_Information.pdf

²
<https://www.astrazeneca.com/media-centre/press-releases/2020/astrazenecas-covid-19-vaccine-authorised-in-uk.html>

³
<https://clinicaltrials.gov/ct2/show/NCT04516746#contacts>

⁴
<https://www.research.ox.ac.uk/Article/2020-07-19-the-oxford-covid-19-vaccine>

⁵
<https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca>

⁶ See ref v

⁷
<https://www.bmj.com/content/371/bmj.m4037>

⁸
<https://www.gov.uk/government/news/jcvi-advises-on-covid-19-vaccine-for-people-aged-under-40>



AstraZeneca / Oxford Covid-19 Vaccine PATIENT INFORMATION LEAFLET

- In April 2021 the NIAC advised it be given only to people aged over 60 after reports of rare blood clotting events emerged⁹
- It is not advised as a booster in the UK or Ireland¹⁰

Doses required: Two separate doses of 0.5ml each. The second dose should be administered between 4 and 12 weeks after the first dose¹¹

ANIMAL TRIALS

In a preliminary trial with six monkeys the vaccine prevented lung damage, but the virus was found to be actively replicating in the nose¹² which indicated that the vaccine did not prevent infection or potential viral transmission.

Experiments with mice and hamsters were also conducted. In the hamster trial an intranasal vaccine produced a higher immune response than the intramuscular vaccine.¹³

HUMAN TRIALS

PHASE 1 - A trial with 1,077 healthy adults aged 18-55 years, 91% Caucasian, began in the UK in April 2020. The placebo group were given the meningitis (MenACWY) vaccine (not an inert saline placebo). People with known underlying conditions were excluded from this trial.

⁹<https://www.rte.ie/news/2021/0412/1209247-coronavirus-vaccine-ireland/>

¹⁰<https://www.gov.uk/government/publications/jcvi-statement-september-2021-covid-19-booster-vaccine-programme-for-winter-2021-to-2022/jcvi-statement-regarding-a-covid-19-booster-vaccine-programme-for-winter-2021-to-2022>

¹¹ See ref v

¹² <https://www.biorxiv.org/content/10.1101/2020.05.13.093195v1.full.pdf>

¹³ <https://www.biorxiv.org/content/10.1101/2020.12.02.408823v1.full.pdf>

PHASE 2/3 - In a single-blind, randomised, controlled, phase 2/3 trial, healthy adults > 18 years were enrolled at two UK clinical research facilities. After two doses of vaccine, the following was reported:

- **Local reactions (pain, redness, swelling of injection site)** reported in 43/49 (88%) participants in the 18–55 years group, 22/30 (73%) in the 56–69 years group and 30/49 (61%) in the 70+ years group
- **Systemic reactions (fever, chills, fatigue, muscle pain, etc)** reported in 42 (86%) participants in the 18–55 years group, 23 (77%) in the 56–69 years group, and 32 (65%) in the 70 + years group
- As of Oct 26, 2020, **13 serious adverse events occurred** during the study period, none of which were considered to be related to the vaccine¹⁴
- By 14 days after the second dose, 208 (>99%) of 209 boosted participants had neutralising antibody responses. T-cell responses peaked at day 14 after a single standard dose.¹⁵

Further trials took place in the UK, Brazil, South Africa and India, with varied placebos (MenACWY vaccine or saline).

Vaccine effectiveness: Published trial data¹⁶ states that between April 23 and Nov 4 2020, 23,848 participants were enrolled in trials. Of these, 11,636 participants (7,548 in the UK, 4,088 in Brazil) were included in the interim primary efficacy analysis. **“Overall vaccine efficacy (effectiveness) across both groups was 70.4%.”**

70.4% appears to have been the average of two different dose regimes (accidental half-dose given in UK trial for first dose) – 62% effectiveness in Brazil trial and 90% effectiveness in UK trial.

¹⁴ <https://pubmed.ncbi.nlm.nih.gov/33220855/>

¹⁵ [https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(20\)32466-1.pdf](https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(20)32466-1.pdf)

¹⁶ [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)32623-4/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32623-4/fulltext)



AstraZeneca / Oxford Covid-19 Vaccine PATIENT INFORMATION LEAFLET

Vaccine safety: 175 severe adverse events (SAEs) occurred in 168 participants, 84 events in the vaccine group and 91 in the control group. **Three SAEs were classified as possibly related to a vaccine:** one in the Covid-19 vaccine group, one in the control group (MenACWY vaccine) and one in a participant who remains masked to group allocation.”¹⁷

Transverse myelitis was mentioned in two severe adverse events (SAEs) that temporarily stopped trials. One was later reported to have undiagnosed multiple sclerosis. One participant died in Brazil; he is said to have received the placebo (MenACWY). A SAE in India has been reported by a trial participant in the media¹⁸ and is currently being investigated.

COST/ STORAGE

This vaccine is the lowest in cost of all three contenders for the UK, at £2.23 [**do we know that this is still the case?**] per dose (based on the EU deal).

It should be stored in a refrigerator (2°C to 8°C), not frozen, making the logistics easier than the BioNTech/Pfizer vaccine. During use it can be stored from 2°C to 25°C.¹⁹

OTHER INFORMATION

¹⁷ <https://pubmed.ncbi.nlm.nih.gov/33306989/>

¹⁸

<https://www.nationalheraldindia.com/health/serum-institutes-covid-19-vaccine-triggers-behavioural-change-in-participant-drug-regulator-silent>

¹⁹

<https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-uk-recipients-on-covid-19-vaccine-astrazeneca>

The trials for the Oxford-AstraZeneca trials have come under some criticism e.g. for the mixed dosing regimens used and for combining multiple different studies.

There is conflicting guidance in place on the interchangeability of vaccines (use of alternative if the same vaccine isn't available for the 2nd dose).

PLEASE DO YOUR OWN RESEARCH

This vaccine received Emergency Use Authorisation from the MHRA on 30th Dec. 2020. This is defined as authorisation for temporary supply. The vaccine does not have a marketing authorisation. **[All this needs checking, as the age restrictions have changed:]**

- It may only be used for individuals aged 18 years and older
- It was not tested on pregnant women
- All trial participants had/have to affirm that they are using “highly effective” contraception 28 days prior to dose 1 through until 60 days after dose 2, because the effects on a foetus are unknown
- A number of provisos relating to this (breastfeeding, etc) apply: please see the Information for UK Recipients²⁰

Further information for UK recipients of the vaccine is available here:

<https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-uk-recipients-on-covid-19-vaccine-astrazeneca>

Summary of the Public Assessment Report for AstraZeneca COVID-19 vaccine

²⁰

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948335/Information_for_UK_recipients_COVID-19_Vaccine_AstraZeneca.pdf



UK Medical Freedom
ALLIANCE

AstraZeneca / Oxford Covid-19 Vaccine PATIENT INFORMATION LEAFLET

<https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/summary-of-the-public-assessment-report-for-astrazeneca-covid-19-vaccine>

Patient Group Direction

<https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2021/01/C1012-patient-group-direction-for-covid-19-vaccine-astra-zeneca-ChAdOx1-5-6-jan-2021.pdf>

Information for Healthcare Professionals on COVID-19 Vaccine AstraZeneca

<https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca>

UKMFA have published a Covid-19 Vaccine Consent Form to help support discussions between the patient and administering health professional about the benefits and risks of a Covid-19 vaccine, to protect both parties in this process www.ukmedfreedom.org/resources/vaccine-documents

For more information about Medical Freedom, Informed Consent and Covid-19 vaccines, please visit our website www.ukmedfreedom.org

You must not rely on the information on our website as an alternative to medical advice from your doctor or other professional healthcare provider and if you have any specific questions about any medical matter, you should consult your doctor or other professional healthcare provider.