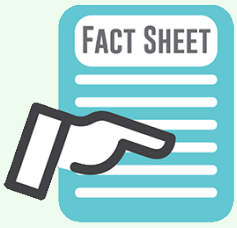

Astra Zeneca Covid vaccine (AZD1222)

DNA based vaccine

Live document - updated 21 February 2021

General Information

AstraZeneca (AZD1222) (ChAdOx1 nCoV-19)

AstraZeneca's AZD1222 coronavirus vaccine candidate, formerly known as **ChAdOx1 nCoV-19**, is made from a weakened version of a common cold virus, hence its original name. While it can cause infection in chimpanzees, the virus was genetically changed so it cannot reproduce/ replicate in humans.

The manufacturer released only a cursory list of ingredients, without including the microgram or milligram amount of each chemical. One 0.5cc injecting includes:

- COVID-19 Vaccine (ChAdOx1-S* recombinant) 5 × 10^10 viral particles (vp) **This product contains genetically modified organisms (GMOs)*
- Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS CoV 2 Spike (S) glycoprotein
- Genetically modified human embryonic kidney (HEK) 293 cell

List of excipients – unknown amounts:

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

This vaccine candidate is of interest because the clinical studies, done in collaboration with the University of Oxford**,** were widely publicized as the first and most promising vaccine. However, in May 2020, it was reported that **all the vaccinated monkeys** treated with the Oxford vaccine became infected when challenged. It remains unclear why the company pressed forward with the renamed, AZD1222 vaccine candidate. Even though the vaccine did not protect the animals from infection, *it did moderate the disease.* Not to let all that research and money go to waste, researchers now believe the shot will be effective against a new viral variant emerging in Britain.

Summary notes from M H R A Public Assessment Report [PAR]

- Authorised by MHRA for temporary supply in UK 29 December2020 under Regulation 174 of the Human Medicines Regulations 2012.
- Temporary authorisation is valid until expressly withdrawn by MHRA or upon issue of a marketing authorisation by MHRA.
- This vaccine remains under review as MHRA continues to receive data from the company as it becomes available, e.g. final study reports for all studies, long-term follow-up efficacy and safety data. Updates to PAR will be provided in due course.
- The vaccine is produced in genetically modified human embryonic kidney [HEK] 293 cells. The vaccine contains genetically modified organisms [GMO].
- For immunisation of individuals 18 years and older.
- intramuscular injection [deltoid muscle].
- Two injections: second injection between 4 and 12 weeks after first injection.
- Final reports for all studies not received [29 December 2020].
- Reproductive toxicity study is ongoing: outcome of reproductive toxicity study in mice is expected in 2021.
- drug substance process validation studies are not yet complete. Full validation study results must be provided once available.
- There is a theoretical concern of vaccine-associated disease enhancement, where use of the vaccine might put vaccinated individuals at risk of worse disease if they later encounter Sars-CoV-2.
- No absorption studies were performed since the route of administration is intramuscular.
- No metabolism studies were performed.
- No excretion studies were performed.
- No single dose toxicity studies have been performed.
- No genotoxicity studies were performed.
- No carcinogenicity studies were performed.
- An evaluation of the impact on embryo fetal development was completed in a dose-range study [490838]. The main GLP embryo-fetal development study [490843] is ongoing with the audited draft report due at the end of January 2021.
- No other toxicity studies have been done.
- A final recommendation on the use in pregnant or lactating women cannot be made by MHRA at this time. The ongoing study should provide more information once it is completed.
- Information provided to healthcare professionals states that the vaccine should only be considered in pregnancy when the potential benefits outweigh any potential risks for the mother and fetus.
- No environmental risk assessment has been undertaken. Consequences of release and persistence of the GMO in the environment are considered by MHRA as negligible.
- No pharmacokinetic data has been submitted.
- A detailed review of neurological adverse events was undertaken which identified the following neurological cases of interest; [a] a new diagnosis of multiple sclerosis with symptom onset 10 days after first dose. [b] a likely case of "short segment inflammatory myelitis" with symptom onset 14 days after second dose, [c] a case of "transverse myelitis" in the control group with symptom onset 54 days after first control dose, [d] six cases of facial paralysis, three in each study group. [e] two cases of trigeminal neuralgia [both in the control group].

- Two deaths were reported in subjects that received the vaccine: one subject died 64 days after vaccination from Pneumocystis jirovecii pneumonia, and one subject died 86 days after their second dose of vaccine from metastatic ovarian cancer. Four deaths occurred in the control group [Covid 19 pneumonia, craniocerebral injury, injury and homicide].
- Vaccine associated enhanced disease is a theoretical risk, which is relevant to all Covid 19 vaccines.
- No data is currently available in immunocompromised subjects or in subjects taking immunosuppressant's.
- No data is available on use of concomitant vaccines, including influenza vaccine.
- The following important potential risks have been identified by MHRA in the Risk Management Plan [RMP], [a] neuroinflammatory disorders, [b] vaccine-associated enhanced disease.
- The following missing information has been identified by MHRA in RMP, [a] use of vaccine in pregnant and breastfeeding women, [b] use of vaccine in subjects with severe immunodeficiency, [c] use of vaccine in subjects with severe and / or uncontrolled underlying disease, [d] use of vaccine with other vaccines, [e] long-term effectiveness and safety.
- The pharmacovigilance plan will investigate whether there is a link between the vaccine and neuroinflammatory disorders, and vaccine associated enhanced disease.
- Long-term real-world data on vaccine effectiveness is included as missing information.

General Notes

Fertility

Like the mRNA-type vaccine, the DNA-based Covid-vaccine has not been seriously and long enough tested to be devoid of risks, or even to know the short- medium and long-term dangers. The AstraZeneca Covid vaccine (AZD1222) also modifies the human genome, and precisely what this may mean for human health and reproduction is unknown. Negative impacts cannot ever be corrected: they are passed on to future generations.

Liability for damages

AstraZeneca has been given indemnity in the UK, which means that people who suffer damage from the vaccine will not be able to sue the company. NHS staff providing the vaccine, as well as manufactures of the drug, are also protected.

Adverse Drug Reaction [ADR]

In October 2020 the MHRA posted a bid request stating that “For reasons of extreme urgency,” they seek “an Artificial Intelligence (AI) software tool to process the expected high volume of Covid-19 vaccine Adverse Drug Reaction (ADRs).” The bid goes on to explain that “it is not possible to retrofit the MHRA’s legacy systems to handle the volume of ADRs that will be generated by a Covid-19 vaccine,” and that this “represents a direct threat to patient life and public health.”

Period 4 January 2021 to 24
January 2021Total reported A D R = 21,032
Deaths = 34

Concerns from medical / scientific profession

The following eminent members of the medical / scientific profession have serious concerns regarding vaccine safety and effectiveness.

Dr Andrew Kaufman,
Dr Hilde De Smet,
Dr Nils R Fosse,
Dr Elizabeth Evans,
Dr Mohammad Adil,
Dr Vernon Coleman,
Prof. Dolores Cahill,
Dr R Zac Cox,
Dr Anna Forbes,
Dr Ralf ER Sundberg,
Dr Johan Denis,
Dr Daniel Cullum,
Moritz von der Borch,
Dr Anne Fierlafijn,
Dr Tom Cowan,
Dr Kevin P. Corbett,
Dr Carrie Madej,
Dr Barre Lando,
Natural Nurse Kate Shemirani,
Pharmacist Sandy Lunoe,
Licensed Acupuncturist Boris Dragin,
Dr Piotr Rubas,
Dr Natalia Prego Cancelo,
Dr Rashid Buttar,
Dr Nour De San,
Dr Kelly Brogan,
Prof. Konstantin Pavlidis,
Dr Sherri Tenpenny,
Journalist Senta Depuydt,
Dr Heiko Santelmann,
Dr Margareta Griesz-Brisson,
Dr Mikael Nordforsa and
Dr Elke F. de Klerk

Definitions

Pharmacovigilance
Plays a key role in the healthcare system through assessment, monitoring, and discovery of interactions amongst drugs and their effects in humans.

Pharmacokinetics
Doses that are in a therapeutic range.

Toxicokinetics
Study of systemic exposure during toxicological experiments. Describes how a toxicant [i.e. a poison] enters the body and reaches a target tissue.

Teratogenicity
A teratogen is an agent that can disturb the development of an embryo or foetus. Teratogens halt the pregnancy or produce a congenital malformation [a birth defect]. Classes of teratogens include radiation, maternal infection, chemicals and drugs.

Genotoxicity
In vitro and in vivo tests designed to detect compounds that induce genetic damage e.g. damage to DNA.

Carcinogenicity
Ability or tendency to produce cancer.