Moderna vaccine

Covid 19 Vaccine Moderna mRNA-1273

Fact Sheet

Live document - updated 21 February 2021

General Information

Moderna (mRNA-1273)
Like Pfizer's vaccine, Moderna's vaccine also uses mRNA as its vehicle for inducing antibody responses to the spike protein. Approved for those 18 years of age and older, the vaccine is given in two doses, (100 mcg in 0.5 cc intramuscular injection) with the second dose given one month (28 days) later, or as close to the recommended interval as possible. This vaccine can be stored for up to six months at -4F (-20C) temperatures. The ingredients in the Moderna vaccine have now been listed on the Moderna Fact Sheet for providers: Moderna Covid 19 Vaccine is a white to off-white suspension for intramuscular injection to be injected 28 days apart. Each 0.5 mL dose of Moderna Covid 19 Vaccine contains:

- Synthetic messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus, 100 mcg (**IMPORTANT:** The Moderna patent states that the mRNA also encodes for the protein, **flagellin, an unapproved vaccine adjuvant** used to stimulate the pro-inflammatory Toll-like receptor 5 (TLR5)
- Lipid: (SM-102, 1,2-dimyristoyl-rac-glycero3-**methoyxy-polyethylene glycol-**2000 [PEG2000-DMG]
- Lipid: 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 93 mg
- Lipid: cholesterol
- tromethamine, 31 mg – this is a prescription medication used to treat metabolic acidosis
- tromethamine hydrochloride, 18 mg
- acetic acid, 0.42 mg
- sodium acetate, 0.12 mg
- sucrose, 43.5 mg

Buried deep inside the Moderna patent is a section that has been ignored by the media and is not mentioned on the Moderna provider fact sheet**.** The mRNA in the Moderna vaccine has been coded to transcribe a protein, flagellin, that is used to enhance the cytokine response of the macrophages.

Either of the currently authorized mRNA COVID-19 vaccines can be used when indicated; ACIP does not state a product preference. However, these two vaccines are **not** interchangeable and both doses of the series should be completed with the same product. Additional doses of either product are not recommended. Both vaccines are completely protected from all liability by the 2005 PREP Act in USA. If a nurse administers the wrong dose, resulting in a serious reaction, even death, there will be no repercussions for the nurse and no compensation provided.

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

- Information in this PAR last updated 18 January 2021.
- On 24 December 2020 the DHSC requested authorisation on a temporary basis under Regulation 174 of Human Medicines Regulations 2012 [HMR 2012]
- Authorised by MHRA for temporary supply in UK 8 January 2021 under Regulation 174 of HMR 2012.
- Authorisation is valid until expressly withdrawn by MHRA or upon issue of a marketing authorisation.
- Authorised for use in adults aged 18 years and above.
- Two-dose vaccine, each 0.5 ml. Recommended second dose 28 days after first dose.
- All reported side effects to be continuously monitored. Additional proactive safety monitoring plan in place by MHRA for all Covid 19 vaccines to enable rapid analysis.
- Final report for all studies not yet received by MHRA.
- Vials are stored at -25 degrees C to -15 degrees C until ready for use.
- Vaccine contains the genetic code for the spike protein of SARS-CoV-2. The lipid nanoparticle delivers the mRNA to cells of the body.
- Vaccine remains under review as MHRA continues to receive data from the company as it becomes available, to include long-term follow-up efficacy and safety data. PAR will be updated accordingly.

- Excipients in vaccine include; trometamol [Tris], trometamol hydrochloride [Tris-Hcl], acetic acid, sodium acetate trihydrate, sucrose and water.
- No secondary pharmacodynamic studies undertaken.
- No safety pharmacodynamic drug interaction studies undertaken.
- The absence of dedicated safety pharmacology studies is considered acceptable by MHRA.
- Pharmacokinetics ?
- No absorption studies undertaken.
- No metabolism studies undertaken.
- No excretion studies undertaken.
- No pharmacokinetic drug interaction studies undertaken.
- No other pharmacokinetic studies undertaken.
- No single dose toxicity studies undertaken.
- No genotoxicity studies undertaken.
- No carcinogenicity studies undertaken.
- No reproductive and developmental toxicity studies undertaken.
- RT-PCR test used to confirm Covid 19 cases in studies.
- Long-term data collection from clinical studies still ongoing.
- Limited experience with use of vaccine in pregnant women.
- Not known whether mRNA vaccine is excreted in human milk.
- Efficacy, safety and immunogenicity of vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. This will be investigated as part of pharmacovigilance plan.
- No data available on use with concomitant vaccine, including influenza vaccine.
- **Risk Management Plan** [RMP] prepared: a legal requirement.
- **Important Identified Risks**: Anaphylaxis.
- **Important Potential Risks**: Vaccine Associated Enhanced Disease, including Vaccine Associated Respiratory Disease.
- **Important Missing Information**:
  - Use in pregnancy and while breastfeeding.
  - Long-term safety.
  - Long-term effectiveness.
  - Use in immunocompromised subjects.
  - Interaction with other vaccines.
  - Use in frail subjects with unstable health conditions and co-morbidities, e.g. Chronic Obstructive Pulmonary Disease [COPD], diabetes, chronic neurological disease, cardiovascular disorders.
  - Use in subjects with autoimmune or inflammatory disorders.
- Information on serious adverse events and medically attended events is being collected for two years following first injection.
- The full relevance of animal studies to human risk with vaccines for Covid 19 remains to be established.

General Notes

Fertility
It is a matter of concern that no reproductive and developmental toxicity studies have been undertaken.

Liability for damages
Moderna 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."

Information on ADR not yet available as vaccine not rolled out in UK to date.

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.