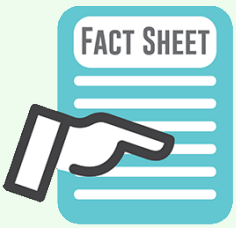

Pfizer / BioNTech Vaccine

mRNA vaccine BNT162b2

Live document - updated 21 February 2021

General Information

Pfizer/BioNTech (BNT162b2)
Pfizer's vaccine – given the tentative name Comirnaty – has been approved for persons 16 years of age and older. The mRNA vaccine consists of two doses (30mcg solution in 0.3cc) given intramuscularly 21 days apart. The vaccine must be stored at -94F (-70C). mRNA is an unstable molecule, which is why it needs to be wrapped in lipid nanoparticles for storage and transportation. But the lipid nanoparticle is exquisitely sensitive to temperature; hence the reason that the vaccine must be stored and transported at extraordinarily low temperatures.
The ingredients found in Pfizer's vaccine include the following:

- ALC-0315 = (4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate)
- ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide
- 1,2-Distearoyl-sn-glycero-3-phosphocholine
- cholesterol
- potassium chloride
- potassium dihydrogen phosphate
- sodium chloride
- disodium hydrogen phosphate dihydrate
- sucrose

Note that none of the ingredients are listed with milligrams dosage. ***Not one of the first three excipients has ever been used in a previously approved vaccine.*** Have they been tested for synergistic toxicity? Has there been stability testing for the breakdown of each ingredient when warmed to room temperature? And what about all those allergic reactions being reported? Have ANY of these chemicals been tested for allergic responses, in humans or even in animals? Pfizer gives explicit instructions on how to mix and administer this injection. While Pfizer and the FDA / MHRA have no idea if this vaccine will prevent infection or even if the antibodies will persist long-term, Pfizer expects to manufacture over 1.3 billion doses worldwide by the end of 2021.

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

- First mRNA vaccine to be authorised for temporary supply and use in the human population.
- Remains under review as MHRA continues to receive data from company as it becomes available.
- Long-term follow-up efficacy and safety data to be assessed at a future date.
- No secondary pharmacology and safety pharmacology studies undertaken.
- No excretion studies have been conducted.
- No pharmacokinetic drug interaction studies have been conducted.
- No single dose toxicity studies have been undertaken.
- No toxicokinetic studies have been performed with the vaccine.
- No genotoxicity studies are planned for BNT162b2.
- No carcinogenicity studies with BNT162b2.
- A combined fertility and developmental study [including teratogenicity and postnatal investigations] in rats is ongoing.
- No prenatal and postnatal development, including maternal function studies have been done.
- No local tolerance studies have been done.
- No other toxicity studies have been done.
- No reproductive toxicity data is available.
- Not known whether the vaccine is safe for pregnant women. Use of vaccine in pregnancy will be investigated as part of pharmacovigilance plan.
- Women breast feeding should not be vaccinated. Not known whether BNT162b2 is excreted in breast milk.
- No environmental risk assessment available.
- Clinical study BNT162-01 ongoing [17 December 2020].
- Clinical study C4591001 ongoing [17 December 2020].
- Subjects with a history of severe adverse reaction associated with a vaccine and / or severe allergic reaction [e.g. anaphylaxis] were excluded from the study.
- Safety data for ongoing studies corresponding to longer follow-up will be submitted at a future date.
- 2 deaths reported in participants that received BNT162b2 in Phase 2 / 3 of study. C4591001: a participant died 3 days after dose 1. A participant experienced cardiac arrest 60 days after dose 2 and died 3 days later. There were 4 deaths in participants that received placebo in Phase 2 / 3.
- 126 participants reported Serious Adverse Event [SAE] during Phase 2 / 3 of study C4591001.
- 120 participants with HIV were included in the phase 3 part of study C4591001. Analysis of safety not yet available for this sub-group.
- Use of immunosuppressed individuals will be investigated as part of the pharmacovigilance plan.
- No data available on use with concomitant vaccines, including influenza vaccines.
- Long-term real-world data on vaccine effectiveness not available.

General Notes

Fertility

Early in December 2020, two leading doctors wrote to the European Medicine Agency, which is responsible for the safety of vaccines, in an attempt to stop human trials of all Covid-19 vaccines, especially the Pfizer/BioNtech Covid 19 mRNA Vaccine BNT162b2. Dr. Michael Yeadon, a former head of Pfizer's respiratory research, and Dr. Wolfgang Wodarg, a health policy advisor, take the view that human testing is still unethical. Among other concerns, Yeadon and Wodart warn that some of the vaccines may prevent the safe development of placentas in pregnant women, resulting in "vaccinated women essentially becoming infertile." "Several vaccine candidates are expected to induce the formation of humoral antibodies against spike proteins of SARS-CoV-2," the doctors wrote. "Syncytin-1 […] which is derived from human endogenous retroviruses (HERV) and is responsible for the development of a placenta in mammals and humans and is therefore an essential prerequisite for a successful pregnancy, is also found in homologous form in the spike proteins of SARS viruses," they continued. "There is no indication whether antibodies against spike proteins of SARS viruses would also act like anti-Syncytin-1 antibodies. However, if this were to be the case this would then also prevent the formation of a placenta which would result in vaccinated women essentially becoming infertile." The doctors suggest that because the Pfizer/BioNTech trial protocol says that "women of child-bearing potential" can take part only if they are not pregnant or breastfeeding and are using contraception, it could take "a relatively long time before a noticeable number of cases of post-vaccination infertility could be observed."

Liability for damages

Pfizer, the owner of the COVID-19 mRNA Vaccine BNT162b2 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 9 December 2020 to 24 January 2021
Total reported A D R = 49,472
Deaths = 107

Concerns from medical / scientific profession

The following eminent members of the medical / scientific profession have serious concerns regarding Covid 19 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.