UK Medical Freedom ALLIANCE

Pfizer/BioNTech COVID-19 Vaccine (Comirnaty) PATIENT INFORMATION LEAFLET

This leaflet should be used alongside the UKMFA general COVID-19 Vaccines Patient Information Leaflet[i] and the supplementary update sheet. It contains general medical information which is not advice and should not be treated as such.

TYPE OF VACCINE & HOW IT WORKS

The Pfizer/BioNTech COVID-19 vaccine (BNT162b2), called Comirnaty, is the **first commercial production of an mRNA vaccine** – a completely new type of biotechnology. This does not work in the same way as conventional vaccines.

mRNA vaccines have previously been attempted for other coronaviruses, e.g. MERS and SARS; however, these were unsuccessful due to high levels of side-effects in the animal studies.

The vaccine uses a **strand of synthetic mRNA**[ii]. mRNA is unstable so it is **packaged inside PEGylated lipid nanoparticles**, tiny lipid particles covered in **PEG** (Polyethylene glycol – a petroleum based chemical). These nanoparticles protect the mRNA and allow it to enter the body's cells after vaccination. PEG is known to trigger anaphylaxis (severe allergy) in some individuals[iii].

When the mRNA enters a cell, it uses the cell machinery, providing instructions to the host cell to produce SARS-CoV-2 spike proteins, which are released into the bloodstream. The immune system recognises these proteins as foreign and produces antibodies against them, believed to provide immunity against a future infection with SARS-CoV-2.

Ingredients: The active substance is **BNT162b2 RNA**. After dilution, the vial contains 6 x 0.3mL doses, with **30 micrograms of mRNA** in each dose. The vaccine also contains **Polyethylene Glycol**/macrogol (PEG) as part of **ALC-0159**.

Other stated ingredients are **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 and water for injections**.[iv]

DOSES & DURATION OF IMMUNITY

Two doses are required for the initial course of treatment. More recently additional, unquantified **booster(s)** have been advised.

The **duration of immunity is short-lived** and now believed to be around 4-6 months[v], hence the addition of booster doses to the schedule.

ANIMAL TRIALS

No animal safety studies have been published for this vaccine. The vaccine was tested on **mice and macaque monkeys to establish efficacy** only (not safety)[vi].

Trials on mRNA vaccines for other coronaviruses resulted in severe side-effects, due to a phenomenon called **Antibody Dependent Enhanced Immunity**[vii]. This occurs when the vaccine-induced antibodies paradoxically cause a **more severe illness with subsequent exposure to the wild virus**. Many animals involved died or became very unwell and human trials did not proceed.

Pfizer reported (see CDC presentation[viii]) a **brief safety study on Wistar rats** with no systemic events identified, however **this study is not publicly available**.

Efficacy studies: both mice and macaques developed antibodies to SARS-CoV-2 following immunisation. After vaccination, when deliberately exposed to SARS-CoV-2, all the macaque monkeys had evidence of infection with SARS-CoV-2 in their noses and airways. **None of the monkeys, in either the vaccinated or placebo**

group, developed symptoms. The animals that received the **vaccine had evidence of SARS-CoV-2 in their noses for 1 day,** while those that received the **placebo had SARS-CoV-2 on nasal swabs on days 1, 3 and 6 after exposure**. As no animals in either group developed symptoms, we cannot infer whether the vaccine would reduce symptoms in humans. **No assessment of transmission was performed.**

HUMAN TRIALS

Phase 1 & 2 Trials:

Across the Phase 1 and 2 trials[ix], **204 people received 2 doses of the BNT162b2 vaccine** (others received a placebo or a potential alternative vaccine). Participants provided a daily diary, for a list of side-effects, over 7 days[x] after receiving the vaccine. Some reported **headaches, muscle and joint pain** which was **debilitating and prevented them from performing even basic daily chores**. Phase 2 **efficacy will be measured for 24 months**, while **safety will be monitored for 6 months**.

Lymphocyte numbers were monitored in the 24 people who received the vaccine in Phase 1**, otherwise no blood tests to assess the potential impact on internal organs or other aspects of health are being conducted** at any point.

Phase 3:

43,538 people had been enrolled in the Phase 3 trial by early December 2020[xi]. **The study does not end until January 2023**; people who take the vaccine should be aware it is still essentially experimental and **awaiting long-term safety data**.

Efficacy:

Pfizer published a **press release stating the vaccine is 95% effective. This efficacy calculation is based on only 181 of the 43,548 participants** (see below).

Of 43,548 trial participants, only **181 people had confirmed cases of symptomatic SARS-CoV-2 infection (COVID-19) -** 1 or more symptoms plus a positive PCR result at least 7 days after the second vaccine dose. Of the 181 "cases", 95% were in the placebo group and 5% in the vaccine group. Several other participants developed COVID-19, but were **excluded from the analysis** due to timing of their symptoms.

Safety:

Of the 43,548 people in this study, **only the first 8,183 people have also completed the electronic diary of local and systemic side effects.** Half of this group received the vaccine, the other half a placebo; therefore, **safety reporting is based on around 4,000 people** receiving the vaccine in this part of the trial.

The **most commonly reported side-effects** were[xii]:

- **Injection site pain 11.2%**
- **Fever 6.1%**
- **Chills 5.3%**
- **Fatigue 5.5%**
- **Headache 5.1%**
- **Muscle pains 4.8%**
- **Joint pains 1.1%**
- **Swollen glands (neck and underarm) 0.3%**
- **Facial paralysis (palsy)** - reported by 4 participants in the vaccine group[xiii]

Limitations of the trials:

The manufacturer's clinical trials did not assess**:**

- ? **Does the vaccine save lives?** (no one died from COVID-19 in the trials in either the placebo or vaccine group)
- ? **Does the vaccine reduce development of severe COVID-19?** (3 cases of severe COVID were reported in the placebo group and 1 in the vaccine group – these numbers are too small to answer the question)
- ? **Does the vaccine prevent transmission?** Emerging, real-world data shows they do not prevent infection or transmission of the virus[xiv]
- ? **Does the vaccine impact blood or organ health?**

UK Medical Freedom ALLIANCE

Pfizer/BioNTech COVID-19 Vaccine (Comirnaty) PATIENT INFORMATION LEAFLET

The following groups were excluded from the original clinical trials:

- **Anyone considered a suicide risk or with mental health disorders**
- **Pregnant and breastfeeding women** – trials are ongoing for these groups
- **Children under the age of 12 –** children's trials are ongoing
- **Anyone with evidence of a prior COVID-19 infection**

OTHER CONCERNS

Little or no published information exists on:

- **Late onset side-effects** - other vaccines have been linked to onset of **autoimmune conditions** (e.g. HPV vaccine - linked with Guillain-Barré syndrome[xv]; Swine Flu vaccine - linked with narcolepsy[xvi] and **neurological problems)**. These conditions may develop weeks, months or even years after vaccination – with no long-term safety data it is impossible to rule out these and other potential long-term side-effects e.g., **infertility, cancers, neurological conditions etc**
- **Several cases of allergy and anaphylaxis** following vaccination were reported in the media in the first few weeks of the global Pfizer Covid vaccine roll-out[xvii]. This MAY be linked to anti-PEG antibodies[xviii].
- The potential for **genetic modification of the host** (risk of DNA being reverse-transcribed from the vaccine mRNA and being incorporated into the host genome) as trials specifically excluded genetic analysis. In February 2022, an in-vitro study found that vaccine mRNA was incorporated into the DNA of human liver cells in the lab, which is a cause for concern and requires further investigation[xix].
- **Autoimmunity** caused by vaccine-induced, cross-reactive antibodies attacking human proteins with similarities to the virus spike protein e.g. **Syncytin-1, a key placental protein, has a very similar structure to the spike protein so vaccine-induced antibodies MAY be cross-reactive with syncytin-1, potentially affecting fertility[xx]**
- RNA's instability means this **vaccine must be handled with care** – guidance for the trials stated that it *"should be prepared and dispensed by an appropriately qualified and experienced member of staff"*

PLEASE DO YOUR OWN RESEARCH AND SPEAK TO YOUR DOCTOR

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

https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-uk-recipients-on-pfizerbiontech-covid-19-vaccine#contents

Package leaflet information for the recipient is here:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/955901/Temporary_Authorisation_Patient_Information_BNT162_6_0_UK_clean.pdf

Summary of product characteristics (usually more detailed than patient leaflets):

https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty#product-information-section

Further information for Healthcare professionals is available here:

https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-healthcare-professionals-on-pfizerbiontech-covid-19-vaccine

UKMFA have published a COVID-19 Vaccine Consent Form to help support discussions between the patient and vaccinator about benefits and risks COVID-19 https://www.ukmedfreedom.org/open-letters/covid-19-vaccine-informed-consent-form

Pfizer/BioNTech COVID-19 Vaccine (Comirnaty)
PATIENT INFORMATION LEAFLET

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.

[i] https://uploads-ssl.webflow.com/5fa5866942937a4d73918723/5fdcb8da3e69e028e9fd95e8_UKMFA_COVID-19_Vaccine_Patient_Information.pdf
[ii] https://www.fda.gov/media/144246/download
[iii] https://assets.website-files.com/5fa5866942937a4d73918723/6011a450fd486937783c2481_Article_on_anapylaxis_in_recipients_of_the_Covid-19_mRNA_vaccines_V4.pdf
[iv] https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-uk-recipients-on-pfizerbiontech-covid-19-vaccine#contents
[v] https://www.nature.com/articles/s41467-021-26672-3.pdf
[vi] https://www.biorxiv.org/content/10.1101/2020.09.08.280818v1
[vii] https://pubmed.ncbi.nlm.nih.gov/32908214/
[viii] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-11/COVID-02-Gruber-508.pdf
[ix] https://clinicaltrials.gov/ct2/show/NCT04368728
[x] https://www.nejm.org/doi/suppl/10.1056/NEJMoa2027906/suppl_file/nejmoa2027906_appendix.pdf
[xi] https://www.nejm.org/doi/full/10.1056/NEJMoa2034577?query=recirc_artType_railA_article
[xii] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-11/COVID-02-Gruber-508.pdf
[xiii] https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf
[xiv] https://papers.ssrn.com/sol3/papers.cfm
[xv] https://www.medicines.org.uk/emc/files/pil.261.pdf
[xvi] https://www.cdc.gov/vaccinesafety/concerns/history/narcolepsy-flu.html
[xvii] https://www.newsweek.com/pfizer-covid-vaccine-allergies-more-expected-white-house-moncef-slaoui-1557129
[xviii] https://www.sciencedirect.com/science/article/pii/S0169409X20301083
[xix] https://www.mdpi.com/1467-3045/44/3/73/htm
[xx] https://2020news.de/en/dr-wodarg-and-dr-yeadon-request-a-stop-of-all-corona-vaccination-studies-and-call-for-co-signing-the-petition/