**Additional Information regarding Pfizer's COVID-19 mRNA Vaccine BNT 162b2**

**What is COVID-19 mRNA Vaccine BNT 162b2 and what is it used for?**

COVID-19 mRNA Vaccine BNT162b2 is a vaccine used for active immunisation to prevent COVID- 19 disease caused by SARS-CoV-2 virus. This vaccine can be given to persons over 16 years of age. The vaccine triggers the body's natural production of antibodies and stimulates immune cells to protect against COVID-19 disease.

**This vaccine is the first vaccine to be approved for use in the UK and will be the vaccine available for the initial vaccination clinics. Oxford University AstraZeneca is still to be approved and there is no date when this will be available as yet**

**What type of Vaccine is the BioNTech COVID-19 Vaccine?**

The Pfizer BioNTech COVID-19 vaccine is an mRNA (messenger ribonucleic acid) vaccine. It contains the genetic sequence (mRNA) for the spike protein which is found on the surface of the SARS-CoV-2 virus, wrapped in a lipid envelope (referred to as a nanoparticle) to enable it to be transported into the cells in the body.

When the vaccine is injected into the body, the mRNA is taken up by the host's cells which translate the genetic information and produce the spike proteins. These are then displayed on the surface of the cell. This stimulates the immune system to produce antibodies and activate T-cells which prepare the immune system to respond to any future exposure to the SARS-CoV-2 virus by binding to and disabling any virus encountered.

As there is no whole or live virus involved, the vaccine cannot cause disease. The mRNA naturally degrades after a few days.

https://www.pfizer.co.uk/behind-science-what-mrna-vaccine

**How was the vaccine made so quickly?**

The COVID-19 vaccine has been rigorously tested for safety and efficacy and has been through all of the usual vaccine trial phases. However, rather than running these sequentially, some of the phases have been run in parallel in order to expedite vaccine production and protection of the population (PHE Nov 20)

See Oxford University Video for additional information:
https://www.youtube.com/watch?v=ddDiyIKUP0M

**Is there any data on side effects/safety?**
Before any COVID-19 vaccine can be authorised for widespread use in the population, the manufacturers have to demonstrate that they are safe and effective.

Tens of thousands of people have already received COVID-19 vaccines in clinical trials; these have shown that no serious adverse reactions to the vaccines were seen in the trial participants who received the vaccines likely to be considered for use in the UK.

Any reactions reported to date have been **similar to those seen following other vaccines such as pain and tenderness at the injection site and fever, headache, muscle aches, and fatigue**

**What are all the possible side effects from the vaccine?**
Like all vaccines, COVID-19 mRNA Vaccine BNT162b2 can cause side effects, although not everybody gets them.

Most side effects are mild or moderate and go away within a few days of appearing. If side effects such as pain and/or fever are troublesome, they can be treated by medicines for pain and fever such as paracetamol.

Side effects may occur with following frequencies:
**Very common:** may affect more than 1 in 10 people

- pain at injection site
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever

**Common:** may affect up to 1 in 10 people

- injection site swelling
- redness at injection site
- nausea

**Uncommon:** may affect up to 1 in 100 people

- enlarged lymph nodes
- feeling unwell

Additional information can be found here: [What to expect after the COVID-19 vaccine: information for HSCWs (publichealthscotland.scot)]

**Is there any information on Effectiveness of the Vaccine?**
Manufacturers of the COVID-19 vaccines also need to show evidence that they will be effective. They can do this by showing a reduction in virus levels in animal studies where the vaccines were used and that people in the trials have made an antibody response to the vaccine. They can also calculate vaccine effectiveness by comparing the number of cases of COVID-19 disease in trial participants who received the COVID-19 vaccine with the number of trial participants who received the placebo or alternative (non-COVID-19) vaccine.

Those running clinical trials will also look at antibody response:

- After one dose and two doses
- At different dosages of the vaccine
- With different time intervals between vaccine doses
- In different age groups

Over time, they will look at how long the antibodies last and the effect on antibody levels if a booster dose is given. They will also look at whether the vaccine just stops people from becoming severely ill or if it stops them spreading the virus too.

As with any vaccine, COVID-19 mRNA Vaccine BNT162b2 may not fully protect all those who receive it. No data is currently available in individuals with a weakened immune system or who are taking chronic treatment that suppresses or prevents immune responses.

**Can the vaccine be given to children and adolescents?**
COVID-19 mRNA Vaccine BNT162b2 is not recommended for children under 16 years.

**How is COVID-19 mRNA Vaccine BNT162b2 is given**
COVID-19 mRNA Vaccine BNT162b2 is given after dilution as an injection of 0.3 mL into a muscle of your upper arm.

**Does the COVID-19 mRNA Vaccine BNT162b2 contain sodium & potassium?**
This vaccine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially ‘potassium-free’. This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium- free’.

**What else does the vaccine contain?**

The BNT162b2 COVID-19 vaccine contains**:**

The active substance is BNT162b2 RNA.

Each does contains 7 micrograms mRNA.

The other 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

**Who are the Manufacturer(s) of this vaccine?**

BioNTech Manufacturing
GmbH
Kupferbergterrasse 17-
19
55116 Mainz, Germany