WHAT IS THE MAIN PURPOSE OF PFIZER VACCINE?

The Pfizer BioNTech COVID-19 vaccine is a messenger RNA (mRNA) vaccine that has both synthetic, or chemically produced, components and enzymatically produced components from naturally occurring substances such as proteins. **The vaccine does not contain any live virus.**

The Pfizer-BioNTech COVID-19 vaccine, named BNT162b2, and known as <u>Comirnaty</u> in the European Union, is a two-dose <u>mRNA vaccine</u> developed by two pharmaceutical industry companies: <u>Pfizer</u> in the United States and <u>BioNTech</u> in Germany.

In December 2020, the Food and Drug Administration (FDA) Trusted Source and World <u>Health Organization (WHO)</u> Trusted Source authorized the vaccine for emergency use in individuals aged 16 years and older, making it the first COVID-19 vaccine to receive emergency use authorization by either organization. The vaccine is currently approved in <u>82</u> countries.

This mRNA vaccine works by providing the body with a set of instructions for creating the spike protein found on the surface of the <u>SARS</u>-CoV-2 virus. The presence of the protein antigen in the body triggers the immune system to produce antibodies, which prepares the body to fight against future infection by the virus itself.

How long after second Pfizer Vaccine Is it effective?

One week after the second dose, the Pfizer-BioNTech vaccine will be 95 per cent effective in preventing COVID-19

Can the Pfizer Covid vaccine give you a rash?

Individuals also commonly reported pain and irritation at the site of the vaccine injection. Additionally, an allergic reaction to certain ingredients in the vaccine may occur. Symptoms of an allergic reaction may include hives, a rash, swelling, and respiratory symptoms.

POINTS TO NOTE:

About the Phase 3 Data from Adolescents 12-15 Years of Age

The trial enrolled 2,260 adolescents 12 to 15 years of age in the United States. In the trial, 18 cases of COVID-19 were observed in the placebo group (n=1,129) versus none in the vaccinated group (n=1,131). Vaccination with BNT162b2 elicited SARS-CoV-2–neutralizing antibody geometric mean titres (GMTs) of 1,239.5, demonstrating strong immunogenicity in a subset of adolescents one month after the second dose.

This compares well (was non-inferior) to GMTs elicited by participants aged 16 to 25 years old (705.1 GMTs) in an earlier analysis. Further, BNT162b2 administration was well tolerated, with side effects generally consistent with those observed in participants 16 to 25 years of age.

The companies plan to submit these data to the FDA and EMA for a requested amendment to the Emergency Use Authorization of BNT162b2 and the EU Conditional Marketing Authorization for COMIRNATY[®] to expand use in adolescents 12-15 years of age as quickly as possible. All participants in the trial will continue to be monitored for long-term protection and safety for an additional two years after their second dose.

Pfizer and BioNTech plan to submit the data for scientific peer review for potential publication.

AUTHORIZED USE IN THE U.S.:

The Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency UseAuthorization (EUA) for active immunization to prevent coronavirus disease 2019(COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)in individuals 16 years of age and older.

However, the vaccine does not contain the virus and cannot cause infection.
Additionally, the mRNA in the vaccine does not have the ability to alter DNA inside cells, as it is a transient molecule and does not enter the nucleus where the DNA is stored.

• Although mRNA vaccines have been studied for many years, they have never before been approved for human use against disease. As a result, members of the public have raised concerns regarding potential unknown side effects.

Update on the Phase 1/2/3 Study in Children 6 months to 11 years' old

Last week, Pfizer and BioNTech dosed the first healthy children in a global Phase 1/2/3 seamless study to further evaluate the safety, tolerability, and immunogenicity of the Pfizer-BioNTech COVID-19 vaccine in children 6 months to 11 years of age. The study is evaluating the safety, tolerability, and immunogenicity of the Pfizer-BioNTech COVID-19 vaccine on a two-dose schedule (approximately 21 days apart) in three age groups:

- Children aged 5 to 11 years,
- 2 to 5 years,
- 6 months to 2 years.
- The 5 to 11-year-old cohort started dosing last week and the companies plan to initiate the 2 to 5-year-old cohort next week.

The Pfizer-BioNTech COVID-19 Vaccine, BNT162b2, has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564 (b) (1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

SUMMARY

- Success of this vaccine has been documented in adolescent age group
- Trials are on from 6months -2 years
- Also in agegroup more than 15 namely 16-25 years.
- These trials in the extra adolescent age groups is a have been done in a desperate attempt to save the young children (including neonates) and adulults upto age of 25

years who are relatively without comorbidities but getting worse affected in the 2^{nd} wave and to hence give a blanket protection.