World Health Organization

The Pfizer BioNTech (BNT162b2) COVID-19 vaccine: What you need to know

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The WHO Strategic Advisory Group of Experts on Immunization (SAGE) has issued interim recommendations for the use of the Pfizer BioNTech (BNT162b2) vaccine against COVID-19. This article provides a summary of those interim recommendations; you may access the full guidance document here.

Here is what you need to know.

According to SAGE, the Pfizer-BioNTech COVID-19 mRNA vaccine is safe and effective. The priority is to start vaccinating health workers at high risk of exposure, followed by older adults, before immunizing the rest of the population.

Who can take the vaccine?

The vaccine is safe and effective for all individuals aged 5 and above. In line with the WHO Prioritization Roadmap and the WHO Values Framework, older adults, health workers and immunocompromised persons should be prioritised.

The Pfizer vaccine can be offered to individuals who have had COVID-19 in the past, but individuals may wish to delay vaccination for 3 months following the infection

Should pregnant and breastfeeding women be vaccinated?

Given the adverse consequences of COVID-19 disease during pregnancy and the increasing data supporting a favorable safety profile of BNT162b2 in pregnancy, WHO recommends the use of BNT162b2 in pregnant individuals. WHO does not recommend pregnancy testing prior to vaccination. WHO does not recommend delaying pregnancy or terminating pregnancy because of vaccination.

Vaccine effectiveness is expected to be similar in breastfeeding women as in other adults. WHO recommends the use of the vaccine in breastfeeding women as in other adults. WHO does not recommend discontinuing breastfeeding because of vaccination.

Who should not take the vaccine?

People with a history of severe allergic reaction to any component of the vaccine should not take it.

Anyone with fever (body temperature over 38.5 ºC) should postpone vaccination until they are afebrile.

Is this vaccine recommended for children and adolescents?

This vaccine is safe for use for those aged 5 and above, with an adjustment in the recommended dosage for those aged 5-11.

WHO recommends that countries should consider using the vaccine in children aged 5 to 17 only when high vaccine coverage with 2 doses has been achieved in the high priority groups as identified in the WHO Prioritization Roadmap.

Children and adolescents aged 5-17 years of age with comorbidities that put them at significantly higher risk of serious COVID-19 disease, should be offered vaccination, alongside other high-risk groups.

Is it safe?

The Global Advisory Committee on Vaccine Safety (GACVS), a group of experts that provides independent and authoritative guidance to WHO on the topic of safe vaccine use, receives and assesses reports of suspected safety events of potentially international impact. In October 2021, the GACVS COVID-19 subcommittee concluded that the mRNA COVID-19 vaccines have clear benefits in all age groups in reducing hospitalizations and deaths due to COVID-19.

How efficacious is the vaccine?

The Pfizer BioNTech vaccine against COVID-19 has an efficacy of 95% against symptomatic SARS-CoV-2 infection.

What is the recommended dosage?

A protective effect starts to develop 12 days after the first dose, but full protection requires two doses which WHO recommends be administered with a 21 to 28-day interval. It is currently recommended that the same product should be used for both doses, when possible.

SAGE recommends that severe and moderately immunocompromised persons, including children, should be offered an additional dose of vaccine, as part of the primary series. This is due to the fact that this group is less likely to respond adequately to vaccination following a standard primary vaccination series and are at higher risk of severe COVID-19 disease.

Studies have shown a high public health impact where the interval has been longer than that recommended by the EUL. Accordingly, countries facing a high incidence of COVID-19 combined with severe vaccine supply constraints could consider delaying the second dose up to 12 weeks in order to achieve a higher first dose coverage in high priority populations.

Is a booster dose recommended for this vaccine?

Booster doses (third dose) is recommended 4-6 months after the 2nd dose given increasing evidence of waning of vaccine effectiveness over time, further compounded by lower vaccine effectiveness against Omicron and Delta that can be restored with a third dose.

The need for, and timing of, booster doses for children aged 5-11 years has not yet been determined.

Can this vaccine be ‘mixed and matched’ with other vaccines?

SAGE accepts two heterologous doses of WHO EUL COVID-19 vaccines as a complete primary series.

For countries considering heterologous schedules, WHO has made recommendations to ensure equivalent or favourable immunogenicity or vaccine effectiveness for heterologous versus homologous schedules:

- **Either of the WHO EUL COVID-19 vectored vaccines (Janssen or AstraZeneca Vaxzervia/COVISHIELD) can be used as a second dose following a first dose of the Pfizer vaccine, dependant on product availability.**
- **The Pfizer vaccine can also be used as a second dose following any of the WHO EUL COVID-19 inactivated vaccines (Sinopharm, Sinovac or Bharat) or any the vectored vaccines (Janssen or AstraZeneca Vaxzervia/COVISHIELD)**

Does it prevent infection and transmission?

There is currently insufficient evidence available related to impact of Pfizer BioNTech vaccine on transmission or viral shedding.

In the meantime, we must maintain and strengthen public health measures that work: masking, physical distancing, handwashing, respiratory and cough hygiene, avoiding crowds, and ensuring good ventilation.

Does it work against new variants?

SAGE has reviewed all available data on the performance of the vaccine in tests to assess efficacy against a variety of variants. These tests indicated that the vaccine was effective against virus variants, though for the Omicron variant, vaccine effectiveness against severe and mild disease after two doses is lower compared to Delta, and waning is more rapid.

SAGE currently recommends the use of the Pfizer BioNTech vaccine according to the WHO Prioritization Roadmap, even if virus variants are present in a country. Countries should assess the risks and benefits taking into consideration their epidemiological situation.

Preliminary findings highlight the urgent need for a coordinated approach for surveillance and evaluation of variants and their potential impact on vaccine effectiveness. As new data become available, WHO will update recommendations accordingly.

How does this vaccine compare to other COVID-19 vaccines in use?

It is impossible to compare vaccines head-to-head due to the different approaches taken in designing the respective studies, but overall, all of the vaccines that have achieved WHO Emergency Use Listing are highly effective in preventing severe disease and hospitalization due to COVID-19.

This webpage was updated on 19 January 2022 to include the latest guidance.

This webpage was updated on 5 January 2022 to update the latest guidance and ensure consistency of information and formatting.

This webpage was updated on 20 April 2021 to ensure consistency of information and formatting.

This article was corrected on 12 January 2021 to remove an erroneous reference relating to pregnancy. WHO does NOT recommend that pregnancy be avoided post-vaccination.

This article was corrected on 10 June to assure consistency of formatting.

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