



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



FREQUENTLY ASKED QUESTIONS

VACCINE SAFETY AND ADVERSE EVENTS

What is the difference between registered vaccines and “emergency use” vaccines?

In normal times, you can only use a vaccine if it is registered with the South African Health Products Regulatory Authority (SAHPRA). SAHPRA will only register a vaccine if:

- all the clinical trials are done, and
- they have studied all the information from the trials to see if it is safe, good quality and effective

In an emergency like the COVID-19 pandemic, SAHPRA can approve an unregistered vaccine to be used for a certain time (emergency use authorisation). This happens when there is enough information that SAHPRA can be confident that the vaccine is safe and effective, but the information is not yet enough to meet all the requirements for full registration.

Is the J&J vaccine still a clinical trial?

No. The clinical trials for the J&J vaccine are done and it is now registered with SAHPRA. J&J will continue to do studies and submit the information to SAHPRA to monitor the safety of the vaccine.

Why were the Chinese vaccines approved so quickly but J&J took so long? Is this because of government’s relationship with China?

CoronaVac (the Chinese vaccine) had completed their clinical trials when they applied to SAHPRA for approval. J&J still had to complete their phase 3 clinical trial before it could be approved. SAHPRA is independent from government. Only vaccines that are approved by SAHPRA can be used, but government is responsible for deciding which vaccine/s will be provided as part of vaccination programmes.

Which vaccine (J&J or Pfizer) is the best?

Both vaccines are safe and will protect you from getting very sick, going to the hospital or dying from COVID-19. The side effects from J&J and Pfizer are similar. They are mild and will go away within three days. Therefore, the best vaccine is the vaccine that is available and offered to you first.

Do I need to be vaccinated if I have previously recovered from COVID-19? Can my body not fight the disease on its own, without suffering the side effects of the vaccine?

Evidence shows that your body’s response when you are sick from COVID-19 is much weaker and shorter than the response to the vaccine. Getting the vaccine will give you a much stronger and longer-lasting immune

response. The side effects of the vaccine are mild and do not last more than a day or two, while getting sick from COVID-19 can cause hospitalisation or death.

Why was the time between the two doses of Pfizer extended?

The time between the Pfizer doses was extended because there is now evidence that if you get the second dose 42 days after the first dose, your body's response is much stronger and lasts longer than when the time is shorter.

Can people with chronic diseases, such as high blood pressure, get the vaccine?

People with chronic diseases such as high blood pressure, heart disease and diabetes are at higher risk of getting severe COVID-19. Therefore, they will benefit the most from getting the vaccine. They should also make sure that their condition is controlled, go for regular check-ups with their healthcare practitioner and take their chronic medication. If you are unsure about your condition, consult with your healthcare practitioner.

I have COVID-19 symptoms – is it safe to get vaccinated?

You should not get the vaccine if you have symptoms of COVID-19 and should rather be tested. If you have COVID-19, you should wait at least 30 days after you have recovered from COVID-19 before you get your vaccine.

How dangerous is an allergic reaction to the vaccine?

Severe allergic reactions to the vaccine are very rare. An allergic reaction usually happens within seconds or minutes after getting the vaccine. This is why ALL people must wait in the observation area for 15 minutes after getting the vaccine to make sure they do not have a major allergic reaction.

For people with allergies, who should NOT get the vaccine?

- 1) Anyone with a history of severe allergic reaction to any ingredient in the vaccine.
- 2) Anyone who is allergic to polyethylene glycol (PEG) should not get the Pfizer vaccine, as it is one of the components.
- 3) Anyone who had a severe allergic reaction after the first dose should not get the second dose of that vaccine.

If you previously had an allergic reaction to a medication or vaccine, but are unsure what specific ingredient caused it, please speak to your healthcare practitioner before getting the vaccine.

For people with allergies, who should speak to their health practitioner before getting the vaccine?

Anyone with a history of allergic reactions to other vaccines or medicines should first speak to their health practitioner to find out which ingredient caused the allergic reaction. The healthcare practitioner will tell you whether it is safe to get the vaccine. If your healthcare practitioner says you can get the vaccine, but your previous reaction to a vaccine or medication was severe, you should be vaccinated in a hospital and be observed for 30 minutes after vaccination. If your previous reaction was not severe, you can get the vaccine at

a normal vaccination site, but you must wait in the observation area for 30 minutes after getting the vaccine to make sure there is no allergic reaction.

Is it safe to get the vaccine if you are allergic to eggs?

Yes. None of the COVID-19 vaccines have any egg proteins. However, you will have to stay in the observation area for 30 minutes after getting the vaccine, instead of the standard 15 minutes, because you have a history of allergies.

I have heard of elderly people dying shortly after getting the vaccine. Is the vaccine safe for the elderly?

The vaccine is both safe and highly effective to prevent severe COVID-19 disease and death. Through the use of the vaccine we are seeing a huge drop in deaths from COVID-19 in the elderly in several countries.

Why do some people still get COVID-19 within two weeks after getting the vaccine?

It takes at least two weeks for the body to develop immunity after getting the vaccine. You are only 'fully vaccinated' 30 days after getting the J&J vaccine or two weeks after the second dose of the Pfizer vaccine. If you are exposed to the virus before you are 'fully vaccinated', you may get the disease.

Also, if you get COVID-19 within a few days after being vaccinated, it means you were already infected before getting the vaccine.

The vaccine also does not completely prevent COVID-19 infection, even after you are 'fully vaccinated' but reduces the risk of severe COVID-19 infection, hospitalisation or death from COVID-19.

Can the vaccine cause COVID-19 disease?

None of the vaccines used in South Africa contains the live virus that causes COVID-19. The vaccine can therefore not make you sick with COVID-19.

Can the Pfizer vaccine cause heart inflammation? Is it safe to give the vaccine to elderly people?

In a very few cases, doctors found heart inflammation in young men who got the Pfizer vaccine. This is a very rare side effect, usually seen within two weeks after the second dose of the vaccine. Common symptoms are chest pain, shortness of breath and an abnormal heartbeat (fast, pounding or fluttering). These symptoms are mostly mild and can be treated, followed by recovery shortly thereafter. People should therefore be aware of the symptoms and immediately seek medical help.