



Sisonke 2 Booster Fact Sheet

11 November 2021

**National Coronavirus
Call Centre**

0800 029 999

Mon-Fri 7am-8pm;
Weekends & public holidays 8am-6pm

Sisonke Desk

0800 014 956 Mon-Fri 7am-6pm

https://redcap.link/sisonke2_ae

Locate an **Accredited
Sisonke Vaccination Site**

<http://findmyjab.co.za>



The Science of Booster Vaccinations

Why is Sisonke providing booster vaccinations to health workers?

New evidence from the ENSEMBLE 2 trial shows excellent levels of protection from two doses of the Ad26COV2.S (Janssen® J&J) vaccine given 56 days apart. This global trial in 31 300 participants found 100% protection against severe-critical COVID-19 and 75% protection against symptomatic (moderate-severe) COVID-19. The booster shot was also shown to increase antibody levels. This information comes at a time where there is concern that there might be some waning of effectiveness 6 months after the first dose of the Ad26COV2.S vaccine (Janssen® J&J). We have seen excellent protection demonstrated in Sisonke to date and continue to monitor durability closely.

The US Federal Drug and Food Administration (FDA) now recommends booster vaccinations for people who received a first dose of the J&J vaccine, as well as all health workers who received Pfizer as their primary vaccine regimen. Health workers are highly exposed to COVID-19 and put their lives on the line to care for others during waves. Vaccines provide the best protection we have against COVID-19. It is important that we offer a booster protection in time for a fourth wave which we expect this coming summer.

Why are booster doses of J&J being provided as part of a study?

The National Vaccination Programme's top priority remains reaching eligible adults who are unvaccinated. As of now less than 40% of adults had been fully vaccinated. To reduce burden on the health system and save lives, the National Programme must focus on providing first vaccinations to as many people, particularly older people, as quickly as possible. Booster doses are otherwise not yet broadly available in South Africa where the priority is to fully vaccinate 70% of the adult population by the end of 2021.

Given the data from the large ENSEMBLE 2 trial, we are now translating this into a real-world effectiveness study to generate more information on the effectiveness of a boost given more 6 months after their first dose. Regulators like our own South African Health Products Authority (SAHPRA) and the National Department of Health take this into account when making decisions about approving vaccine boosters. SAHPRA has provided approval for Sisonke participants to receive boosters as part of a follow-up study (Sisonke 2 Booster) on the basis that there is excellent safety data, immunogenicity data and good efficacy data from clinical trials. Real-world vaccine performance, as monitored in the study, will help SAHPRA and the National Department of Health make informed choices about boosting other adults in 2022.

I have heard that the National Department might be rolling our booster vaccinations anyway. What are the plans and what booster vaccines will they be offering?

These plans are provisional. Booster vaccinations with Comirnaty® (Pfizer-BioNTech) full-dose (two shots) or half-dose vaccines (one shot) are under discussion. Globally there is support for both homologous (same vaccine) and heterologous (different vaccines) boosting regimens, although the only booster regimen currently approved by SAHPRA is a homologous JnJ regimen as part of the Sisonke 2 Booster study.

Booster vaccinations with full-dose or half-dose Comirnaty® (Pfizer-BioNTech) may be forthcoming for health workers in the following weeks and months although this has not yet been confirmed. In addition, the SAHPRA and the NDOH will need to review the safety data of mixing vaccines as well as make an assessment as to whether these mix and match combinations are more effective than homologous boosting and what the overall advantage is of doing it this way. More information may be forthcoming from other regions as well.

Your decision to take up a J&J booster vaccination as part of Sisonke 2 is entirely voluntary and requires that you weigh up your occupational exposure to COVID-19, personal vaccine preference and timing of the fourth wave. We understand that this can be a tough decision but hope that this fact sheet provides more information to assist you.

What does the science say about two-dose J&J and mRNA regimens?

Data shows that a full-dose of Pfizer (two vaccinations at least 21 days apart) is more effective than just one single dose of J&J vaccine in the short term. However, we know that antibody responses after a mRNA vaccine wane from around 4 months, necessitating a third dose or boost, whereas immune responses for the J&J vaccine, while lower in the short-term, are sustained up until 8 months, and may require a boost at that time.

The two dose J&J regimen shows short term efficacy that matches the peak efficacy ever reported for Pfizer and Moderna vaccines and is not an inferior vaccine regimen. It impacts the immune system differently to mRNA vaccines. Immune studies that have compared vaccine responses suggest that it may have greater effects on cell-mediated immunity (not measured by antibody response) and may well show better and more durable long-term protection.

Immune studies looking at immune responses following initial J&J and subsequent Pfizer boosting also confirm increased antibody levels. However, there is still insufficient safety and effectiveness data on this particular regimen (J&J-Pfizer). Authorities are reviewing data on a Pfizer boost in people who had a first dose of the AstraZeneca vaccine – also a viral vector vaccine but decisions are yet to be made.

Sisonke 2 Booster Study Information

Am I eligible to participate in Sisonke 2?

If you received a first dose of the JnJ vaccine as part of Sisonke and are over the age of 18 years you will be invited to receive a booster vaccination. Health workers who are pregnant or breastfeeding can safely take part.

If you received a first dose of JnJ outside the Sisonke study will not be invited. If you experienced a serious side-effect, serious allergic reaction or neurological abnormality after the first dose of the vaccine, we ask that you please be in touch with our safety team to complete a detailed evaluation and if appropriate, carefully monitored, booster vaccination.

A small number of people have a history of heparin-induced or vaccine-induced thrombocytopenia (low platelets). These people cannot repeat a J&J vaccination.

Prior medical conditions are in general not an exclusion criterion although we would like to evaluate participants with a history of certain conditions on an individual basis. These include:

- History of cerebral venous sinus thrombosis (clot in the brain)
- Antiphospholipid syndrome
- Any clotting event that followed your first J&J vaccination.

You can contact our safety team directly through the Sisonke Desk or via the Sisonke Vaccination Site champion. Specifically, we wish to reassure our participants living with HIV that the booster dose is safe.

I have already accessed a booster dose of a vaccine. Can I still take part in Sisonke 2?

Unfortunately no - we are aware that some health workers have accessed unauthorised booster doses of vaccines. At this time safety information on a J&J-Pfizer-J&J regimen is absent and so we cannot offer you a booster. Using multiple ID documents to access unauthorised vaccines means authorities cannot track safety properly. The National Department of Health strongly condemns this practice which may also affect your Vaccination Passport.

When I sign consent what am I agreeing to?

You are agreeing to receive a full dose booster shot of the Ad26COV2.S vaccine (Janssen® J&J) given at least six months after your first dose. You are also agreeing to having your medical record data reviewed at regular intervals to assess the safety and effectiveness of the vaccine. The study continues up to the end of May 2023. This information is collected in two ways. Should you experience a serious side-effect or usual vaccine side-effects ('reactogenicity') that do not go away after 3 days you are requested to contact the Sisonke Desk so that a safety physician can follow you up and ensure you receive any investigations or care you might need. The Sisonke Desk is open Mondays to Fridays from 07H00 to 18H00 and additional doctors have been added to the team for the duration of the booster vaccinations. You can also reach the Sisonke Desk by clicking on the link which will be sent to you via SMS after your booster dose. The link is:

https://redcap.link/sisonke2_ae

The second way data are collected is through passive surveillance. Vaccination status, COVID-19 hospitalisations and all deaths registered in the country are tracked weekly by the Sisonke research team through databases such as EVDS, the National Health Laboratory Service and DATCOV using your ID or passport number. If you are identified as having had a breakthrough infection or being admitted with COVID-19 they will be in touch with you and your attending doctors to ensure your safety and best possible care.

I experienced a bad side-effects after my first dose and am concerned. What should I do?

Many people experienced usual side-effects after the first vaccine including tenderness at the injection site, headache, fever, nausea and dizziness which started around 6 hours after vaccination and resolved within 1-3 days. The good news is that these usual vaccine side-effects are less noticeable after the second dose of the J&J vaccine. This is also the case for other viral vector vaccines like AstraZeneca but different to mRNA vaccines when one may feel worse after the second dose.

Rare side effects are uncommon and include severe allergy ('anaphylaxis') which presents immediately following vaccination and a rare clotting disorder known as Thrombotic (clots) Thrombocytopenia (low platelets) Syndrome (TTS) which presents 3 days to 4 weeks after vaccination. TTS was first described with the AstraZeneca and later with JnJ. Risk factors that may predict this condition have still not been clearly established.

Being aware of the symptoms of TTS can be helpful and ensure people are correctly managed and severe outcomes avoided. Symptoms manifest after 3 days (so after usual vaccine side-effects have resolved) and in the first month and include:

- A new, severe headache especially with vomiting
- Blurred vision, muscle weakness or difficulty speaking
- Swelling of arms and legs
- Severe abdominal pain that does not go away
- A rash of tiny red spots around the site of injection
- A painful or cold leg
- Chest pain or shortness of breath

If you develop these symptoms following vaccination you should immediately seek care and inform them of your recent vaccination. Your provider must send an urgent platelet count, avoid heparin (medication often used to dissolve clots) and make immediate contact with the Sisonke Desk so we can assign specialists to help manage you safely.

If you are one of the few people who experienced a severe side-effect or allergic reaction that required a doctor visit or admission, please be in touch with our Sisonke Desk and we will ensure you receive a personalised assessment to guide your booster vaccination.

I experienced an allergic reaction to a vaccine in the past. What should I do?

Please be in touch with a staff member at the Vaccination Site or our Sisonke Desk. Very few people experience such a serious allergy to vaccines that they cannot safely receive a booster vaccine. Detailed guidelines are available to help medical personnel undertake an assessment of your allergy history and if need be, refer to you to specialist staff for vaccination. You will be observed for a period of 15-30 minutes following vaccination and if needed, all National Vaccination Centres have the right equipment and skilled personnel to manage a severe reaction. Booster doses are not associated with an increase in allergic reactions.

I had COVID-19 after my first dose of JnJ vaccine. Should I still get a booster dose?

You will still get extra benefit from a booster vaccination if you had COVID-19 after your first dose. If you have tested positive for COVID-19 in the past 30 to 35 days, we recommend that you wait for at least 30 days after you tested positive. If you required admission because of COVID-19, we recommend that you discuss the timing of boosting with your health provider.

When can I get my booster?

Booster vaccinations will be available at selected Vaccinated Sites from Wednesday 10 November until mid-December. We will ensure a minimum period of 6 months between vaccinations.

What can I expect before I receive my booster?

You can expect to receive a SMS invitation to the Sisonke 2 study. The invitation will contain two links. The first is to the South African Medical Research Council website where you will be asked to read a participant information leaflet. Please take your time to read this carefully and know that participation is entirely voluntary and that your health care will not be compromised in any way should you decided to participate.

Should you wish to take part you will be required to answer 12 questions. Please complete the consent process in one sitting. You will then receive a new vaccination voucher starting with the letters BD- (Booster Dose).

Please work with your facility manager to plan the date of your jab. Up to 400 sites in the public and private sector will be providing Sisonke booster vaccinations ensuring easy access for all Sisonke participants. You can identify an accredited Sisonke Vaccination Site by visiting the second link provided in the invitation: <http://findmyjab.co.za>

What can I expect at the vaccination site?

You must arrive at the Vaccination Site with your voucher code and your identity book or passport. We encourage participants to bring their original vaccination card as well. You will receive a full dose of the J&J vaccine alongside usual attendees at the site. You will be observed for 15-30 minutes following vaccination and receive a new vaccination card and information sheet to take home.

What can I expect after my booster vaccination?

You can expect mild symptoms starting 6 hours after vaccination and lasting no longer than 1-3 days. These include the same symptoms as following the first dose such as tenderness at the injection site, headache, fever and dizziness but should be milder than following your first dose.

You will receive a SMS confirming your booster vaccination and weekly reminders to be on the alert for side-effects and report them quickly. Your central Vaccination Record will be updated to show that you have received a booster vaccination.

I changed my cell phone number after the first dose. How can I ensure I receive an invite?

Please phone the National Coronavirus Call Centre and ask an operator to update your Vaccination Record with your new number. You can also email the Call Centre at: info@vaccinesupport.org.za

You will be required to submit a copy of your identity document.

I haven't yet received a SMS invite. What should I do?

SMS invitations started flowing from 5pm on Tuesday 9 November. Participants who received their first dose early in Sisonke will receive their invitations first. If you have not received a SMS invitation by Monday 22 November please contact the National Coronavirus Call Center and ask them to check your contact details. If correct, please request that you are referred to the Sisonke team.