Guidance for Healthcare Professionals

SPIKEVAX® (SARS-Cov-2 mRNA vaccine)

This guidance is to provide the information of SPIKEVAX® to the Healthcare Professionals administering vaccine (vaccine providers). If further information is requested, please refer the full prescribing information.

1. Description of COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle and body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

2. What SPIKEVAX® is and what it is used for

SPIKEVAX® is a vaccine used to prevent COVID-19 caused by SARS-CoV-2. It is given to adults aged 18 years and older. The active substance in SPIKEVAX® is mRNA encoding the SARS-CoV-2 Spike protein, which is embedded in lipid nanoparticles.

This vaccine induces the immune response against the SARS-CoV-2 Spike protein and provides the protective effect against COVID-19.

As SPIKEVAX® does not contain the virus to generate the immunity, it cannot give you COVID-19.

3. Nature and contents of container

SPIKEVAX® is a white to off white dispersion supplied in a transparent vial. It may contain white or translucent product-related particulates that are visually identifiable.

Pack size: 10 multi-dose vials/Pack

4. Storage and Handling

Do not use this vaccine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Store in the original carton to protect from light as frozen between -25°C to -15°C.

Do not store on dry ice or below -40°C. Use of dry ice may subject vials to temperatures colder than -40°C.

After thawing, do not refreeze.

Vials may be stored refrigerated between 2°C to 8°C for up to 30 days prior to first use, and may be between 8°C to 25°C up to 12 hours.

Chemical and physical in-use stability has been demonstrated for 6 hours at 2°C to 25°C after initial puncture. But from a microbiological point of view, the product should be used immediately. Discard punctured vial after 6 hours.

After the first dose has been withdrawn, record the date and time of discard on the SPIKEVAX® vial label.

5. Dosing and Schedule

SPIKEVAX® is administered intramuscularly as a series of two doses (0.5 mL each) 4 weeks apart.

There are no data available on the interchangeability of the SPIKEVAX® with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of the SPIKEVAX® should receive a second dose of the SPIKEVAX® to complete the vaccination series.

6. Dose preparation

The SPIKEVAX® multiple-dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration following one of the instructions below.

Thaw in Refrigerator

- Thaw in refrigerated conditions between 2°C to 8°C for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.

Thaw at Room Temperature

- Alternatively, thaw at room temperature between 15°C to 25°C for 1 hour.

Once thawed the vaccine should not be re-frozen.

Swirl vial gently after thawing and between each withdrawal. **Do not shake or dilute.**

7. Administration

Withdraw dose of vaccine from the vial using a new sterile needle and syringe for each injection to prevent transmission of infectious agents. The dose in the syringe should be used immediately.

Visually inspect each dose of the SPIKEVAX® in the dosing syringe prior to administration.

The white to off-white suspension may contain white or translucent product related particulates. During the visual inspection,

- Verify the final dosing volume of 0.5 mL.
- Confirm there are no other particulates and that no discoloration is observed.
- Do not administer if vaccine is discolored or contains other particulate matter.

Administer the SPIKEVAX® intramuscularly.

An additional overfill is included in each vial to ensure that 10 doses of 0.5 mL can be delivered. Depending on the syringes and needles used for each dose, there may not be sufficient volume to extract more than 10 doses. Irrespective of the type of syringe and needle:

- Each dose must contain 0.5 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and contents.
- Do not pool excess vaccine from multiple vials.

In order to improve the traceability of the vaccine, the name and the batch number of the administered product should be clearly recorded.

8. Contraindication

Do not administer the SPIKEVAX® to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the SPIKEVAX® (Refer Full Prescribing Information).

9. General Precautions

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the SPIKEVAX®.

For the recipients with a history of severe hypersensitivity reactions including anaphylaxis, it is required to monitor them at least for 15 minutes after administration.

Monitor SPIKEVAX® recipients more than 15 minutes for the occurrence of immediate adverse reactions.

Very rare cases of myocarditis and pericarditis have been observed following vaccination with SPIKEVAX®. These cases have primarily occurred within 14 days following vaccination, more often after the second vaccination, and more often in younger men. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general.

Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis.

Vaccinees should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination.

Healthcare professionals should consult guidance and/or specialists to diagnose and treat this condition.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the SPIKEVAX®.

The SPIKEVAX® may not protect all vaccine recipients from COVID-19.

10. Use in pregnant or breast-feeding women

There is limited experience with use of SPIKEVAX® in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development. Administration of SPIKEVAX® in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus. It is unknown whether SPIKEVAX® is excreted in human milk.

11. Adverse reactions

Adverse Reactions in Clinical Trials

Adverse reactions reported in a clinical trial following administration of the SPIKEVAX® include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site. (Refer the Full Prescribing Information)

Adverse Reactions in Post-Authorization Experience

Anaphylaxis and other severe allergic reactions, myocarditis and pericarditis have been reported following administration of the SPIKEVAX® during vaccination outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the SPIKEVAX®.

12. Use with other vaccines

There is no information on the co-administration of the SPIKEVAX® with other vaccines.

13. Information to provide to vaccine recipients/caregivers

As the vaccination provider, you must communicate to the recipient or their caregiver, that full prescribing information about the SPIKEVAX® is provided via websites.

For information on clinical trials that are testing the use of the SPIKEVAX® for active immunization against COVID-19, please see www.clinicaltrials.gov.

Inform the recipient or their caregiver of the date when the recipient needs to return for the second dose of SPIKEVAX®.

14. Additional information

Adverse event reporting: KDCA website (https://nip.kdca.go.kr) or call center (1339)
Medical inquiry: 080 001 4589

This guidance for Healthcare Professionals was reviewed by MFDS.
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