FREQUENTLY ASKED QUESTIONS (FAQ) ABOUT SPIKEVAX COVID-19 mRNA VACCINE

Q1: What vaccine is being registered?
A1: The Drug Control Authority (DCA) in its 362nd meeting has granted Moderna Biotech, Spain's for SPIKEVAX 0.2MG/ML DISPERSION FOR INJECTION COVID-19 mRNA VACCINE (nucleoside modified) (Product Registration Holder: Zuellig Pharma Sdn Bhd; Manufacturer: Rovi Pharma Industrial Services, S.A., Spain) a CONDITIONAL REGISTRATION on 5th August 2021.

SPIKEVAX 0.2MG/ML DISPERSION FOR INJECTION COVID-19 mRNA VACCINE (nucleoside modified) contains 100mcg of messenger RNA (mRNA) (embedded in SM-102 lipid nanoparticles) in a single 0.5mL dose.

Q2: What are the conditions of the registration?
A2: Since the application was based on rolling submission of the latest data, the Product Registration Holder (PRH) will need to ensure all outstanding documents are submitted and deemed satisfactory by National Pharmaceutical Regulatory Agency (NPRA) according to the timeline given. This includes all conditions that have been listed by the European Medicines Agency (EMA).

Apart from that, the PRH is required to monitor the safety profile of the registered vaccine and inform NPRA as soon as possible of any untoward events. The PRH is also required to conduct all activities planned under the Risk Management Plan (RMP) as well as submit a Monthly Safety Summary Report to NPRA.

The validity of this conditional approval is one (1) year. During this period, the DCA will periodically be updated with all necessary information related to the quality, safety and efficacy of this vaccine. The registration can be revoked if the conditions are not fulfilled by the PRH or if the benefit over risk of the vaccine is no longer deemed beneficial.

Q3: Why is SPIKEVAX granted conditional registration?
A3: Clinical studies for SPIKEVAX COVID-19 mRNA VACCINE are currently still ongoing. The current final analysis provided clearly shows a positive benefit over risk and hence making this available to the nation. However, further monitoring of the efficacy and safety will be needed to ensure that the benefit over risk of this vaccine remains positive.

Q4: Who can be given SPIKEVAX?
A4: SPIKEVAX COVID-19 mRNA VACCINE is indicated for the active immunization to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals **18 years of age and older**.

The use of this vaccine should be in accordance with the recommendations by the Ministry of Health Malaysia.

Q5: Who may be given SPIKEVAX?
A5: At the moment, there is limited clinical evidence to support vaccination in these populations: immunocompromised, autoimmune disorders, pregnant or breastfeeding women. However, the decision to use the vaccine in these populations should be made in close consultation with a healthcare professional after considering the benefits and risks.

Q6: Who can't be given SPIKEVAX?
A6**:** SPIKEVAX should not be given to individuals who are known to have allergic reactions to any of the active ingredients or excipients [SM-102 (heptadecan-9-yl 8-{(2-hydroxyethyl) [6-oxo-6 (undecyloxy)hexyl] amino} octanoate, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), Cholesterol, 1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000 DMG), Trometamol, Trometamol hydrochloride, Sodium acetate trihydrate, acetic acid, and sucrose)] in the vaccine.

The second dose of the vaccine should not be given to individuals who had a severe allergic reaction after the first dose of this vaccine.

Please consult your doctor if you:
- have any form of allergies, bleeding disorder, or taking any blood-thinning medications
- recently or currently receiving treatment for cancer, organ or stem cell transplantation
- had a previous history of COVID-19 infection,
- had previously received another COVID-19 vaccine (whether during an immunisation program or was involved as a subject in a COVID-19 clinical study) or previously received passive antibodies therapy for COVID-19

Q7: How is SPIKEVAX given?
A7: SPIKEVAX should be injected into the deltoid muscle of the upper arm in a course of 2 doses (0.5mL each), 28 days apart.

Q8: How well does SPIKEVAX prevent COVID-19?
A8: In the final analysis of Phase III clinical trial (P301), the vaccine was 94.1% (onset of at least 14 days after 2nd dose vaccination) effective in preventing symptomatic COVID-19 disease.

Q9: How long can SPIKEVAX provide protection?
A9: As the clinical trial is still currently ongoing, no data is available to inform about the duration of protection that the vaccine will provide. This however will be made known once updated data is available.

Q10: Can people who have already had COVID-19 get SPIKEVAX?

A10: Available data indicates that SPIKEVAX is safe when given to people with evidence of prior COVID-19 disease. Since previously infected individuals can be at risk of COVID-19 (i.e. reinfection), vaccination may be offered to them. The need for when the vaccination after a SARS CoV-2 infection to be given will be determined by COVID-19 Immunisation Task Force (CITF).

Q11: Can children receive SPIKEVAX?

A11: Currently in Malaysia, the vaccine is indicated for individuals aged 18 years and above. This is because there is limited data to determine the effectiveness and safety of this vaccine in those under 18 years old. Hence, children below the age of 18 **should not take** the vaccine until further data is made available.

Q12: What are the side effects of SPIKEVAX?

A12: SPIKEVAX can cause the following side effects:

- Very common side effects (may affect more than 1 in 10 people): headache, nausea, vomiting, muscle ache, joint ache and stiffness, pain or swelling at the injection site, fatigue, chills, fever and lymphadenopathy (enlarged lymph nodes in the underarm region).
- Common side effects (may affect up to 1 in 10 people): rash, injection site redness or hives.
- Uncommon side effects (may affect up to 1 in 100 people): itchiness at the injection site.
- Rare side effects (may affect up to 1 in 1,000 people): temporary one-sided facial drooping (Bell's palsy) and swelling of the face (may occur in people who have had facial cosmetic injections).
- Very rare side effects (may affect up to 1 in 10,000 people): inflammation of the heart muscle (myocarditis) (higher in younger males) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain.
- Unknown side effects (cannot be estimated from the available data): hypersensitivity reactions
- There is a remote chance that the vaccine could cause a severe allergic reaction (anaphylaxis). A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. Signs of a severe allergic reaction can include difficulty in breathing, swelling of your face and throat, a fast heartbeat, a bad rash all over your body or dizziness and weakness.

  Recipients will be monitored 15-30 minutes after the administration of this vaccine at the vaccination centre. Those who have experienced anaphylaxis to the first dose of SPIKEVAX should not take the second dose. Please get further advice from your doctor.

During the marketing of SPIKEVAX in Malaysia, NPRA will monitor its use to ensure effectiveness and safety. Please inform your healthcare providers or report any side effects to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers > Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Q13: What should I do after I am vaccinated?
A13: All individuals should continue to follow the preventive measures as recommended. Practice the **3Ws** (Wash, Wear, Warn), avoid the **3Cs** (Crowded space, Confined space, Close conversation), get vaccinated and boosted and practice **TRIIS** (Test, Report, Isolate, Inform and Seek Treatment).

For further information regarding **SPIKEVAX COVID-19 mRNA VACCINE***, please refer to the Package Insert and Patient Information Leaflet.*
https://quest3plus.bpfk.gov.my/pmo2/detail.php?type=product&id=MAL21086001ACZ

Date of revision: 28 March 2022