**FREQUENTLY ASKED QUESTIONS (FAQ) ABOUT JANSSEN COVID-19 VACCINE**

**Q1: What vaccine is being registered?**

A1: The Drug Control Authority (DCA) in its 361th meeting has granted Johnson & Johnson Sdn Bhd's JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION a CONDITIONAL REGISTRATION on 16th July 2021.

JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION contains adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein ( Ad26.COV2-S), not less than 8.92 $\log_{10}$ infectious units (Inf.U).

**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 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 soonest possible of any untoward events. The PRH is also required to conduct all activities planned under the Risk Management Plan (RMP) as well as submitting 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 JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION granted a conditional registration?**

A3: Clinical studies for JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION are currently still on-going. The current final analysis provided clearly show a positive benefit over risk and hence making this available to the nation. However, further monitoring of the efficacy and safety will be needed in order to ensure that the benefit over risk of this vaccine remains positive.

**Q4: Who can be given JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION?**

A4: JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION 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 can't be given JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION?**

JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION should not be given to individuals who are known to have allergic reactions to any of the active ingredients or excipients [(2-hydroxypropyl-β-cyclodextrin (HBCD), Citric acid monohydrate, ethanol, hydrochloric acid, Polysorbate-80, sodium chloride, sodium hydroxide, trisodium citrate dihydrate) in the vaccine as well as individuals with rare genetic disorder called capillary leak syndrome.

**Q6: Can the following populations receive JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION?**

A6: At time of approval, there is insufficient clinical evidence to support vaccination in these population: immunocompromised and persons affected by autoimmune disorders. However, these recommendations may change as more clinical data is obtained. Please speak to your doctor to identify if you may be a suitable candidate to receive the vaccine.

**Q7: If I have the following conditions, or receiving or have received these treatments, can I receive the vaccine?**

A7: 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

You may receive the vaccine even if you have the above conditions. However, please speak with your doctor before deciding if you are a suitable candidate.

**Q8: How is JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION given?**

A8: JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION should be injected into the deltoid muscle of the upper arm as a single 0.5mL dose.

**Q9: How well does JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION prevent COVID-19?**

A9: In the interim analysis of the phase III clinical trial (COV3001), the vaccine was at least 66.9% (onset of at least 14 days after vaccination) and 66.1% (onset of at least 28 days after vaccination effective in preventing symptomatic COVID-19 disease following a single dose.

**Q10: How long can JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION provide protection?**

A10: 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.

**Q11: Can people who have already had COVID-19 get JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION?**

A11: Available data indicate that JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION is safe when given in 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.

**Q12: Can pregnant or breastfeeding women receive JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION?**

A12: Pregnant women were excluded in the clinical trials. Since no data on the safety and efficacy of this vaccine is available in these population, current evidence is unable to make recommendation for these groups until further available data is obtained. However, please speak to your doctor to identify if you may be a suitable candidate to receive the vaccine. In addition, it is unknown whether the vaccine would be excreted in human milk.

**Q13: Can children receive JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION?**

A13: Currently in Malaysia, the vaccine is indicated for individuals 18 years of age and older. This is because there is not enough 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.

**Q14: What are the side effects of JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION?**

A14: JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION can cause the following side effects:

- Very common side effects (may affect more than 1 in 10 people): headache, nausea, muscle aches, pain where the injection is given and feeling very tired.
- Common side effects (may affect up to 1 in 100 people): redness or swelling where the injection is given, chills, joint pain, cough and fever.
- Uncommon side effects (may affect up to 1 in 1,000 people): rash, muscle weakness, arm or leg pain, feeling weak, feeling generally unwell, sneezing, sore throat, back pain, tremor and excessive sweating.
- Rare side effects (may affect up to 1 in 10,000 people):allergic reaction and hives.
- Very rare (may affect less than 1 in 10,000 people): blood clots in combination with low level of blood platelets.

- Unknown side effects (cannot be estimated from the available data): severe allergic reaction.

During marketing of JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION 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)].

**Q15: Can JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION cause thromboembolic events (blood clots) following vaccination?**
A15: A combination of blood clots and low levels of 'platelets' (cells that help blood to clot) in the blood has been observed very rarely following vaccination with COVID-19 Vaccine Janssen. This includes severe cases with blood clots, including in unusual locations, such as the brain, liver, bowel and spleen in some cases in combination with bleeding. These cases occurred within the first three weeks following vaccination and occurred mostly in women below 60 years of age. Fatal outcome has been reported.
Seek immediate medical attention, if you experience severe or persistent headaches, seizures (fits), mental status changes or blurred vision, unexplained skin bruising beyond the site of vaccination which appear a few days after vaccination, pinpoint round spots beyond the site of vaccination, develop shortness of breath, chest pain, leg pain, leg swelling, or persistent abdominal pain. Inform your healthcare provider that you have recently received JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION.

**Q16: What should I do after I am vaccinated?**
A16: All individuals should continue to follow the country's SOP. Practice the 3Ws (**Wash**, **Wear**, **Warn**) and avoid the 3Cs (**Crowded** space, **Confined** space, **Close** conversation).

*For further information regarding JANSSEN COVID-19 VACCINE SUSPENSION FOR INJECTION, please refer to the Package Insert and Patient Information Leaflet.*
https://quest3plus.bpfk.gov.my/pmo2/detail.php?type=product&id=MAL21076097ACZ

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