

## **IMPORTANT MEDICINE SAFETY INFORMATION**

26 October 2021

**Dear Healthcare Professional,**

### **COVID-19 VACCINE JANSSEN: RISK FOR IMMUNE THROMBOCYTOPENIA (ITP) AND VENOUS THROMBOEMBOLISM (VTE)**

Janssen Pharmaceutica (Pty) Ltd as directed by the South African Health Products Regulatory Authority (SAHPRA) would like to inform you about the risk of Immune Thrombocytopenia (ITP) and Venous Thromboembolism (VTE), associated with the use of COVID-19 Vaccine Janssen.

The Professional Information (PI) of the COVID-19 Vaccine Janssen will be updated to appropriately reflect the above safety information.

#### **Summary**

##### **1. Immune thrombocytopenia (ITP):**

- **Cases of ITP, some with very low platelet levels (<20,000 per  $\mu$ L), have been reported very rarely, usually within the first four weeks after receiving COVID-19 Vaccine Janssen. This included cases with bleeding and cases with a fatal outcome. Some of these occurred in individuals with a history of ITP.**
- **If an individual has a history of ITP, the risks of developing low platelet levels should be considered before vaccination, and platelet monitoring is recommended after vaccination.**
- **Individuals should be alert to signs and symptoms of ITP, such as spontaneous bleeding, bruising or petechiae.**
- **Individuals diagnosed with thrombocytopenia within 3 weeks after vaccination with COVID-19 Vaccine Janssen should be actively investigated for signs of thrombosis to assess a potential diagnosis of thrombosis with thrombocytopenia syndrome (TTS) that requires specialised clinical management.**

##### **2. Venous thromboembolism (VTE):**

- **Venous thromboembolism has been observed rarely following vaccination with COVID-19 Vaccine Janssen.**

- **The risk of VTE should be considered for individuals with increased risk for thromboembolism.**
- **Healthcare professionals should be alert to the signs and symptoms of VTE. Those vaccinated should be instructed to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg pain, leg swelling, or persistent abdominal pain following vaccination.**
- **Individuals who present with thrombosis within 3 weeks of vaccination should be evaluated for thrombocytopenia to assess a potential diagnosis of thrombosis with thrombocytopenia syndrome (TTS) that requires specialised clinical management.**

The benefits of vaccination continue to outweigh the risks.

### **Background on the safety concern**

COVID-19 Vaccine Janssen suspension for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 18 years of age and older.

#### **1. Immune thrombocytopenia (ITP)**

Although there was no imbalance of thrombocytopenia in clinical trials, review of post-marketing cases support ITP being an adverse drug reaction following vaccination with the COVID-19 Vaccine Janssen.

Analysis of key cases and literature suggests individuals with a medical history of ITP might be at an increased risk of decreased platelets and symptomatic ITP following vaccination with the Covid-19 vaccine Janssen. If an individual has a history of ITP, the risks of developing low platelet levels should be considered before vaccination, and platelet monitoring is recommended after vaccination.

#### **Advice to Healthcare professionals**

- Healthcare professionals should be alert to the signs and symptoms of thrombocytopenia.
- Those vaccinated should be instructed to seek prompt medical attention if they experience spontaneous bleeding, skin bruising (petechia) beyond the site of vaccination after a few days.
- Individuals diagnosed with thrombocytopenia within 3 weeks after vaccination with COVID-19 Vaccine Janssen should be actively investigated for signs of thrombosis to assess a potential diagnosis of thrombosis with thrombocytopenia syndrome (TTS) that requires specialised clinical management.

## **2. Venous thromboembolism (VTE)**

Venous thromboembolism has been observed rarely following vaccination with COVID-19 Vaccine Janssen. This should be considered for individuals at increased risk for venous thromboembolism.

During the double-blind period (median follow-up 123 days) of an ongoing phase 3 study (COV3001), venous thromboembolic events were observed in 26/21,894 (0.1%) of individuals who received COVID-19 Vaccine Janssen and 9/21,882 (0.04%) of individuals who received placebo. Of these, venous thromboembolic events were observed within 28 days in 8 individuals who received COVID-19 Vaccine Janssen and in 4 individuals who received placebo. Deep vein thrombosis and pulmonary embolism were mostly observed (21 individuals who received COVID-19 Vaccine Janssen and 8 individuals who received placebo during the entire double-blind phase). The majority of events were reported in individuals with at least one predisposing risk factor for venous thromboembolism.

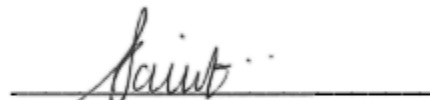
In another ongoing phase 3 study (COV3009, 15,708 individuals receiving the vaccine and 15,592 placebo), there was no increase in venous thromboembolic events among individuals who received the COVID-19 Vaccine Janssen (median follow-up time 70 days).

### **Advice to Healthcare Professionals**

- Healthcare professionals should be alert to the signs and symptoms of VTE.
- Those vaccinated should be instructed to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg pain, leg swelling, or persistent abdominal pain following vaccination.
- Individuals who present with thrombosis within 3 weeks of vaccination should be evaluated for thrombocytopenia to assess a potential diagnosis of thrombosis with thrombocytopenia syndrome (TTS) that requires specialised clinical management.
- Healthcare professionals are urged to report all suspected adverse events following immunisation or product quality issues associated with the use of COVID-19 Vaccine Janssen to SAHPRA via Med Safety App that can be downloaded into a smart mobile phone through google Play or App store. For more information on Med Safety App, please visit SAHPRA website.
- Alternatively, reporting can be done via the eReporting link available on the SAHPRA website ([www.sahpra.org.za](http://www.sahpra.org.za)). Additionally, the ADR reporting form accessible via the SAHPRA website at <https://www.sahpra.org.za/documents/12e54dcaADRForms.pdf> can be completed and emailed to [adr@sahpra.org.za](mailto:adr@sahpra.org.za).
- For more information on ADR reporting, please contact the SAHPRA vigilance unit at [pvqueries@sahpra.org.za](mailto:pvqueries@sahpra.org.za) or alternatively use the contact details below:

PRODUCT	ACTIVE INGREDIENT	REGISTRATION NUMBER	CONTACT DETAILS Pharmacovigilance Unit	CONTACT DETAILS Medical Information
COVID-19 VACCINE JANSSEN	COVID-19 vaccine (Ad26.COV2-S [recombinant])	55/30.5/0849	Tel: +2711 518 7100 Fax: +2786 687 8942 or +2711 518 7108 Email: <a href="mailto:AdverseEventZA@its.jnj.com">AdverseEventZA@its.jnj.com</a>	Janssen COVID-19 Vaccine Dedicated Line Tel: +27 21 672 2331 E-mail: <a href="mailto:JGCC_EMEA@its.jnj.com">JGCC_EMEA@its.jnj.com</a>

Yours sincerely



Sara Cowie

**RESPONSIBLE PHARMACIST**