IMPORTANT MEDICINE SAFETY INFORMATION:
COVID-19 VACCINE JANSSEN

19 May 2021

Dear Healthcare Professional

COVID-19 VACCINE JANSSEN: RISK OF THROMBOSIS IN COMBINATION WITH THROMBOCYTOPENIA

Janssen Pharmaceutica (Pty) Ltd, as directed by the South African Health Products Regulatory Authority (SAHPRA) would like to inform you about the risk of thrombosis in combination with thrombocytopenia, 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

- **A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed following vaccination with COVID-19 Vaccine Janssen. A causal relationship with the vaccine is considered plausible.**
- **These cases occurred within the first three weeks following vaccination, and mostly in women under 60 years of age.**
- **No specific risk factors have been identified at this stage.**
- **Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia.**

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.

A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed following vaccination with COVID-19 Vaccine Janssen. This includes cases of severe venous thrombosis at unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis concomitant with thrombocytopenia. These cases occurred within the first three weeks following vaccination, and mostly in women under 60 years of age. Fatal outcome has been reported. The mechanism for the occurrence of these thrombotic events is not yet defined and no specific risk factors have been identified at this stage.

European Medicines Agency's (EMA's) Pharmacovigilance Risk Assessment Committee, PRAC, performed a thorough investigation including a review of case reports of blood clots

JANSSEN PHARMACEUTICA (PTY) LTD.
(Reg. No. 1980/011122/07)
2 Medical Road
Halfway House
Midrand, 1685
South Africa
✉ 785939
Sandton
2146
South Africa
☎(011) 518-7000
Orders: IHS 0860-655-600
Telefax: (011) 518-7104
www.janssen.com

and thrombocytopenia in individuals who received the vaccine. A causal relationship with the vaccine is considered plausible. Based on the current evidence, SAHPRA in line with the PRAC has recommended an update to the product information to reflect the current knowledge of this safety issue. This comprises an update of the warning section, as well as inclusion of thrombosis in combination with thrombocytopenia as an adverse reaction with a frequency of very rare.

Advice to healthcare professionals

- Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia which are shortness of breath, chest pain, leg swelling, or persistent headaches and abdominal pain, following vaccination.
- Healthcare professionals should advise those vaccinated to consult a healthcare professional if they develop any of the above-mentioned signs and symptoms.
- Additionally, those who receive the vaccine should be advised to consult a healthcare professional promptly when experiencing neurological symptoms including severe or persistent headaches or blurred vision, or if experiencing skin bruising (petechia) beyond the site of vaccination after a few days.
- Thrombosis in combination with thrombocytopenia requires specialised clinical management. Healthcare professionals should consult applicable guidance and/or consult specialists (e.g., haematologists, specialists in coagulation) to diagnose and treat this condition.
- 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. The App 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). 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.
- For more information on ADR reporting, please contact the SAHPRA vigilance unit at 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: AdverseEventZA@its.jnj.com	**Janssen COVID-19 Vaccine Dedicated Line** **Tel:** +27 21 672 2331 **E-mail:** JGCC_EMEA@its.jnj.com

Yours sincerely

Sara Cowie
RESPONSIBLE PHARMACIST

JANSSEN PHARMACEUTICA (PTY) LTD.
(Reg. No. 1980/011122/07)
2 Medical Road
Halfway House
Midrand, 1685
South Africa
✉ 785939
Sandton
2146
South Africa
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