



Media Statement

29 November 2021

Johnson & Johnson to Evaluate its COVID-19 Vaccine Against New Omicron COVID-19 Variant

Since the emergence of the COVID-19 pandemic, Johnson & Johnson (the Company) has been closely monitoring newly emerging COVID-19 variants. In collaboration with academic groups in South Africa and around the world, the Company has been evaluating the effectiveness of its COVID-19 vaccine across variants,^{1,2} including now at the new and rapidly spreading Omicron variant. The Company is testing blood serum from participants in completed and ongoing booster studies to look for neutralising activity against the Omicron variant. In addition, the Company is pursuing an Omicron-specific variant vaccine and will progress it as needed.

"The new Omicron variant highlights the importance of continued surveillance, testing and vaccination to prevent hospitalisations and deaths from COVID-19. We remain confident in the robust humoral and cell-mediated immune responses elicited by COVID-19 Vaccine Janssen demonstrated by the durability and breadth of protection against variants to date in clinical studies," said Mathai Mammen, MD, PhD, Global Head, Janssen Research & Development LLC, Johnson & Johnson. "We will not be complacent. Building on our long-term collaboration with scientists on the ground in South Africa and the ongoing real world effectiveness studies being conducted with COVID-19 Vaccine Janssen, we will work together to generate new data on Omicron. In parallel, we have begun work to design and develop a new vaccine against Omicron and will rapidly progress it into clinical studies if needed."

For more information on the Company's multi-pronged approach to helping combat the pandemic, visit: <https://www.janssen.com/emea/our-focus/infectious-diseases-vaccines/respiratory-infections/covid-19>.

#

Authorised Use

The Janssen COVID-19 vaccine has been granted Conditional Marketing Authorisation in the EU for active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.³

IMPORTANT SAFETY INFORMATION

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE JANSSEN COVID-19 VACCINE?³

Tell the vaccination provider about all of your medical conditions, including if you:

- have ever had a severe allergic reaction after injection of any other vaccine.
- have ever fainted following any needle injection.
- you have a severe infection with a high temperature (over 38C). However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.
- you have a problem with bleeding or bruising, or if you are taking anticoagulant medicine (to prevent blood clots).

This statement has been adapted for use in EMEA regions.

- your immune system does not work properly (immunodeficiency) or you are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants or cancer medicines).

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before you receive this vaccine.

WHO SHOULD NOT GET THE JANSSEN COVID-19 VACCINE?³

You should not get the Janssen COVID-19 Vaccine if you:

- you are allergic to the active substance or any of the other ingredients of this vaccine.
- you have a previous diagnosis of capillary leak syndrome, (a condition causing fluid leakage from small blood vessels).

HOW IS THE JANSSEN COVID-19 VACCINE GIVEN?³

Your doctor, pharmacist or nurse will inject the vaccine into the muscle – usually in the upper arm.

WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?³

Like all vaccines, COVID-19 Vaccine Janssen can cause side effects, although not everybody gets them. Most of the side effects occur in the 1 or 2 days of getting the vaccination.

Get medical attention **immediately** if within 3 weeks of vaccination you get any of the following symptoms:

- experience severe or persistent headaches, blurred vision, mental status changes or seizures (fits);
- develop shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain;
- notice unusual skin bruising or pinpoint round spots beyond the site of vaccination.

Get **urgent** medical attention if you get symptoms of a severe allergic reaction. Such reactions may include a combination of any of the following symptoms:

- feeling faint or light-headed
- changes in your heartbeat
- shortness of breath
- wheezing
- swelling of your lips, face, or throat
- hives or rash
- nausea or vomiting
- stomach pain.

Seek **immediate** medical attention, if you experience symptoms that may be signs of blood disorders including venous thromboembolism, thrombosis with thrombocytopenia syndrome or immune thrombocytopenia: severe or persistent headaches, seizures (fits), mental status changes or blurred vision, unexplained bleeding, 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 COVID-19 Vaccine Janssen.³

Very rare cases of capillary leak syndrome (CLS) have been reported following vaccination with COVID-19 Vaccine Janssen. At least one affected patient had a previous diagnosis of CLS. CLS is a serious, potentially fatal condition causing fluid

This statement has been adapted for use in EMEA regions.

leakage from small blood vessels (capillaries) resulting in rapid swelling of the arms and legs, sudden weight gain and feeling faint (low blood pressure). Seek **immediate** medical attention if you develop these symptoms in the days following vaccination.³

Seek immediate medical attention if you develop weakness and paralysis in the extremities that can progress to the chest and face (Guillain-Barré syndrome). This has been reported very rarely after vaccination with COVID-19 Vaccine Janssen.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?³

If you experience a severe allergic reaction, please seek immediate medical care. Afterwards you should report adverse reactions to Janssen in your region. Contact details can be found here:

www.janssen.com/sites/www_janssen_com/files/janssen_site_q3_2020.pdf.

Coagulation disorders

- *Thrombosis with thrombocytopenia syndrome*: A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with COVID-19 Vaccine Janssen. This includes severe cases of venous thrombosis at unusual sites such as cerebral venous sinus thrombosis (CVST), splanchnic vein thrombosis as well as arterial thrombosis concomitant with thrombocytopenia. Fatal outcome has been reported. These cases occurred within the first three weeks following vaccination, and mostly in individuals under 60 years of age. 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.
- *Venous thromboembolism*: Venous thromboembolism has been observed rarely following vaccination with COVID-19 Vaccine Janssen (see section 4.8). This should be considered for individuals at increased risk for VTE.
- *Immune thrombocytopenia*: Cases of immune thrombocytopenia with very low platelet levels (<20,000 per μL) have been reported very rarely after vaccination with COVID-19 Vaccine Janssen, usually within the first four weeks after receiving COVID-19 Vaccine Janssen. This included cases with bleeding and cases with fatal outcome. Some of these cases occurred in individuals with a history of immune thrombocytopenia (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.

Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia. 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. Additionally, anyone with neurological symptoms including severe or persistent headaches, seizures, mental status changes or blurred vision after vaccination, or who experiences skin bruising (petechia) beyond the site of vaccination after a few days, should seek prompt medical attention.³

Very rare cases of capillary leak syndrome (CLS) have been reported in the first days after vaccination with COVID-19 vaccine Janssen, in some cases with a fatal outcome. A history of CLS has been reported. CLS is a rare disorder characterised by acute episodes of oedema mainly affecting the limbs, hypotension, haemoconcentration and hypoalbuminaemia. Patients with an acute episode of CLS following vaccination require prompt recognition and treatment. Intensive supportive therapy is usually warranted. Individuals with a known history of CLS should not be vaccinated with this vaccine.³

Guillain-Barré syndrome (GBS) has been reported very rarely following vaccination with COVID-19 Vaccine Janssen. Healthcare professionals should be alert of GBS signs

This statement has been adapted for use in EMEA regions.

and symptoms to ensure correct diagnosis, in order to initiate adequate supportive care and treatment and to rule out other causes.³

For more information, the EMA Summary of Product Characteristics is available at: www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_en.pdf.

About Johnson & Johnson

At Johnson & Johnson, we believe good health is the foundation of vibrant lives, thriving communities and forward progress. That's why for more than 130 years, we have aimed to keep people well at every age and every stage of life. Today, as the world's largest and most broadly-based healthcare company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body and environment within reach of everyone, everywhere. We are blending our heart, science and ingenuity to profoundly change the trajectory of health for humanity. Learn more at www.janssen.com/emea. Follow us at @JanssenEMEA.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension. Learn more at www.janssen.com/emea. Follow us at @JanssenEMEA.

Cautions Concerning Forward-Looking Statements

This media statement contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding development, manufacture and distribution of our COVID-19 vaccine. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of the Janssen Pharmaceutical Companies, and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2021, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

###

This statement has been adapted for use in EMEA regions.

References

- 1 Polinski J. et al. Effectiveness of the Single-Dose Ad26.COV2.S COVID Vaccine. medRxiv 2021.09.10.21263385; doi: <https://doi.org/10.1101/2021.09.10.21263385>.
- 2 Sisonke. Available at: <https://sacoronavirus.co.za/wp-content/uploads/2021/08/Sisonke-Provisional-Results-6-August-2021GG2.pdf>. Last accessed: November 2021.
- 3 European Medicines Agency. Janssen vaccine COVID-19 Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_en.pdf. Accessed November 2021.