Prescribing Information: Nuvaxovid JN.1 ▼ COVID-19 vaccine (recombinant, adjuvanted) dispersion for injection in pre-filled syringe

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentation: One dose (0.5 mL) pre-filled syringe contains 5 micrograms of the SARS-CoV-2 (Omicron JN.1) spike protein* and is adjuvanted with Matrix-M. Adjuvant Matrix-M containing per 0.5 mL dose: Fraction-A (42.5 micrograms) and Fraction-C (7.5 micrograms) of *Quillaja saponaria* Molina extract. *Produced by recombinant DNA technology using a baculovirus expression system in an insect cell line that is derived from Sf9 cells of the *Spodoptera frugiperda* species.
Indication: Nuvaxovid JN.1 is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older. Nuvaxovid JN.1 should be used in accordance with official recommendations.
Dosage and Administration: Nuvaxovid JN.1 is administered intramuscularly as a single dose (0.5 mL) for individuals 12 years of age and older regardless of previous vaccination status. For individuals who have previously been vaccinated with a COVID-19 vaccine, Nuvaxovid JN.1 should be administered at least 3 months after the most recent dose of a COVID-19 vaccine. *Immunocompromised individuals*: Additional doses may be administered to individuals who are severely immunocompromised in accordance with national recommendations. *Paediatric population*: The safety and efficacy of Nuvaxovid JN.1 in children aged less than 12 years have not yet been established. No data are available. *Elderly population*: No dose adjustment is required in elderly individuals ≥ 65 years of age. Nuvaxovid JN.1 is for intramuscular injection only, preferably into the deltoid muscle of the upper arm. The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.
Contraindications: Hypersensitivity to the active substance or to any of the excipients listed in SmPC.
Warnings and precautions: *Hypersensitivity and anaphylaxis*: Events of anaphylaxis have been reported with Nuvaxovid. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine. Close observation for at least 15 minutes is recommended following vaccination. An additional dose of the vaccine should not be given to those who have experienced anaphylaxis to a prior dose of Nuvaxovid. *Myocarditis and pericarditis*:There is an increased risk of myocarditis and pericarditis following vaccination with Nuvaxovid. These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis and should consult guidance and/or specialists to diagnose and treat this condition. *Anxiety-related reactions*: Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation, or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting. *Concurrent illness*: Vaccination should be postponed in individuals suffering from an acute severe febrile illness or acute infection. The presence of a minor infection and/or low-grade fever should not delay vaccination. *Thrombocytopenia and coagulation disorders*: As with other intramuscular injections, the vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals. *Immunocompromised individuals*: The efficacy, safety, and immunogenicity of the vaccine has been assessed in a limited number of immunocompromised individuals. The efficacy of Nuvaxovid JN.1 may be lower in immunosuppressed individuals. *Duration of protection*: The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials. *Limitations of vaccine effectiveness*: Individuals may not be fully protected until 7 days after their vaccination. As with all vaccines, vaccination with Nuvaxovid JN.1 may not protect all vaccine recipients. *Excipients*: This vaccine contains less than 1 mmol of sodium (23 mg) and less than 1 mmol of potassium (39 mg) per dose; that is to say, it is essentially sodium-free and potassium-free. Polysorbate 80:This medicine contains 0.05 mg of polysorbate 80 per dose. Polysorbates may cause allergic reactions.
Interactions: Concomitant administration of Nuvaxovid JN.1 with other vaccines has not been studied.
Fertility, pregnancy and lactation: There is limited experience with use of Nuvaxovid in pregnant women. Administration of Nuvaxovid JN.1 in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus. It is unknown whether Nuvaxovid JN.1 is excreted in human milk. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.
Adverse Reactions: Very common: Headache, nausea or vomiting, myalgia, arthralgia, injection site tenderness, Injection pain, fatigue, malaise. Common**:** Injection site redness, injection site swelling, pyrexia, pain in extremity. Not known (cannot be estimated from the available data): Anaphylaxis, paraesthesia, hypoaesthesia myocarditis, pericarditis. *Prescribers should consult the SmPC in relation to other adverse reactions.*
List price: Packs of 10 single dose pre-filled syringes without needle: £710.00
Legal Category: POM
Marketing Authorisation Number: PL 04425/0919
Marketing Authorisation Holder: Sanofi , 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK.
Further information is available from: ***UK:*** Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT uk-medicalinformation@sanofi.com.
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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to the Sanofi drug safety department on Tel: 0800 0902 314. Alternatively, send via email to UK-drugsafety@sanofi.com