NEW DRUGS

SARS-CoV-2 rS (NVX-CoV-2373) vaccine

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Approved indication: prevention of COVID-19

Nuvaxovid (Biocelect)
multidose vials containing 5 microgram SARS-CoV-2 spike protein in adjuvanted suspension

SARS-CoV-2 rS, commonly referred to as Novavax, is the fifth vaccine to be provisionally approved in Australia for the prevention of COVID-19 in people 18 years of age and over. Its mechanism of action differs from that of the other vaccines. This vaccine is based on a genetically engineered form of the SARS-CoV-2 spike protein. It also contains an adjuvant to enhance the immune response of B and T cells.

The vaccine is supplied in multidose vials that should be stored at 2–8 °C. Each vial contains ten doses of 0.5 mL. The vaccine is given by intramuscular injection, with a second dose three weeks later.

A phase II trial took place in South Africa around the time the Beta variant of the virus emerged. This placebo-controlled trial randomised 4406 healthy adults, but, as approximately 30% of them already had antibodies against SARS-CoV-2, efficacy was assessed in 2684 seronegative participants who received two doses of the vaccine. Symptomatic COVID-19 developed in 1.1% (15/1357) of the vaccine group and 2.2% (29/1327) of the placebo group.[1]

A phase III trial in the United Kingdom randomised 15,187 adults to receive the vaccine or a placebo. Efficacy was assessed in 14,039 participants who were seronegative and received two doses. Symptomatic infection occurred, at least seven days after the second dose, in 0.14% (10/7020) of the vaccine group and 1.4% (96/7019) of the placebo group. Vaccine efficacy was calculated to be 89.7%. None of the fully vaccinated participants required hospital admission.[2]

Within the UK trial, a group of 431 participants was injected with influenza vaccine at the same time as their first dose of SARS-CoV-2 rS or placebo. Although there was no difference in the immune response to the influenza vaccine, there was a reduced response to the SARS-CoV-2 rS vaccine. Symptomatic COVID-19 developed in 1% (2/191) of the vaccine group and 4% (8/195) of the placebo group. Vaccine efficacy against COVID-19 was calculated to be 74.8% overall and 87.5% in participants under 65 years of age.[3]

A phase III trial in North America randomised 29,949 adults. Two doses of vaccine were given to 17,312 seronegative participants and 8140 received injections of placebo. After a median follow-up of three months, there were 14 cases (0.1%) of COVID-19 in the vaccinated group and 63 cases (0.8%) in the placebo group. Vaccine efficacy was calculated to be 90.4%. All cases of COVID-19 in the vaccinated group were mild.[4]

In the phase III trials, adverse reactions were more frequent following vaccination than in the placebo groups. Reactions were more common after the second dose, in younger people and in participants who received simultaneous influenza vaccine.[2-4] The most frequent reactions were injection-site tenderness (75%) or pain (62%). Systemic adverse effects reported in the trials included headache, arthralgia, myalgia and fatigue. The adverse reactions lasted for an average of one or two days.[2,4] Uncommon adverse events include hypertension and myocarditis. As anaphylaxis is a potential adverse reaction, patients should be observed for at least 15 minutes after being vaccinated.

When SARS-CoV-2 rS was evaluated, the median duration of follow-up after the second dose was 70 days. The phase III trials began before the current viral variants of concern emerged. Information about the efficacy and safety of this vaccine will therefore continue to evolve. At present, it is not approved for use in children or for booster doses. In theory this vaccine could be given in pregnancy but there are currently more data about using other COVID-19 vaccines during pregnancy and lactation.

T manufacturer provided the AusPAR and the product information

REFERENCES

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The Transparency Score is explained in New drugs: transparency, Vol 37 No 1, Aust Prescr 2014;37:27.

At the time the comment was prepared, information about this drug was available on the websites of the Food and Drug Administration in the USA, the European Medicines Agency and the Therapeutic Goods Administration.

Some of the views expressed in the following notes on newly approved products should be regarded as preliminary, as there may be limited published data at the time of publication, and little experience in Australia of their safety or efficacy. However, the Editorial Executive Committee believes that comments made in good faith at an early stage may still be of value. Before new drugs are prescribed, the Committee believes it is important that more detailed information is obtained from the manufacturer's approved product information, a drug information centre or some other appropriate source.