

Elasomeran

Approved indication: prevention of COVID-19

Spikevax (Moderna)

5 mL multidose vials containing 0.2 mg/mL

Elasomeran is the fourth COVID-19 vaccine to be given provisional approval in Australia. It is indicated to prevent COVID-19 in individuals 12 years old and over.

Like the BNT162b2 COVID-19 vaccine (made by Pfizer), elasomeran is a messenger RNA (mRNA-1273) vaccine. The RNA encodes for a modified form of the spike protein of the coronavirus. It is encapsulated in lipid nanoparticles to enable the RNA to be taken into cells after intramuscular injection. The cells produce the spike protein which then induces an immune response which includes neutralising antibodies.

Preliminary investigations,¹ including some patients over the age of 56 years,² established the dose regimen to be used in a randomised phase III trial.³ This was two doses of 100 micrograms of mRNA (0.5 mL) given 28 days apart.

The ongoing phase III trial in the USA has reported its results for people followed up for a median of 63 days after the second injection.³ The per-protocol analysis included 14,134 adults who received the two doses of the vaccine and 14,073 who received a saline placebo. Efficacy was assessed by the occurrence of symptomatic COVID-19 at least 14 days after the second injection. Eleven cases occurred in the vaccine group compared to 185 cases in the placebo group. This gives a vaccine efficacy of 94.1% for the prevention of symptomatic infection. The efficacy was similar across all age groups. Elasomeran had an efficacy of 100% against severe infection as the 30 cases that had severe COVID-19, including one death, were all in the placebo group.

Adverse reactions at the injection site were more frequent with the vaccine than with placebo (88.6% vs 18.8% after the second injection).³ These effects included pain, tenderness, erythema and induration and may have a delayed onset. There have been cases of anaphylaxis, so people need to be observed after vaccination. More common adverse reactions include fatigue, headache, myalgia and arthralgia. The frequency and severity of these adverse effects

was greater after the second dose of vaccine. They persist for an average of three days. Myocarditis and pericarditis may be rare adverse effects.

Elasomeran has to be stored between -25 °C and -15 °C. Thawed vials should be stored at 2 °C to 8 °C until used. Each multidose vial contains enough vaccine for 10 doses (0.5 mL). Dilution is not required. The deltoid muscle is the preferred site for injection.

Like all the vaccines against COVID-19, the efficacy and safety data for elasomeran are incomplete. For example, children and pregnant women were not included in the phase III trial and there was a limited number of immunocompromised patients.³ The efficacy against different viral strains and the duration of protection is unknown. A small study suggests that elasomeran produces higher antibody concentrations than the BNT162b2 vaccine in people over 50 years old.⁴

manufacturer did not respond to request for data

REFERENCES

1. Jackson LA, Anderson EJ, Roupael NG, Roberts PC, Makhene M, Coler RN, et al; mRNA-1273 Study Group. An mRNA vaccine against SARS-CoV-2 – preliminary report. *N Engl J Med* 2020;383:1920-31. <https://doi.org/10.1056/NEJMoa2022483>
2. Anderson EJ, Roupael NG, Widge AT, Jackson LA, Roberts PC, Makhene M, et al; mRNA-1273 Study Group. Safety and immunogenicity of SARS-CoV-2 mRNA-1273 vaccine in older adults. *N Engl J Med* 2020;383:2427-38. <https://doi.org/10.1056/NEJMoa2028436>
3. Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R, et al; COVE Study Group. Efficacy and safety of the mRNA-1273 SARS-CoV-2 vaccine. *N Engl J Med* 2021;384:403-16. <https://doi.org/10.1056/NEJMoa2035389>
4. Richards NE, Keshavarz B, Workman LJ, Nelson MR, Platts-Mills TAE, Wilson JM. Comparison of SARS-CoV-2 antibody response by age among recipients of the BNT162b2 vs the mRNA-1273 vaccine. *JAMA Netw Open* 2021;4(9):e2124331. <https://doi.org/10.1001/jamanetworkopen.2021.24331>

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](#).

First published
6 September 2021
<https://doi.org/10.18773/austprescr.2021.048>

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