NEW DRUGS

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Related articles:
BNT162b2 vaccine for prevention of COVID-19
ChAdOx1-S vaccine for prevention of COVID-19

The new drug commentaries in *Australian Prescriber* are prepared by the Editorial Executive Committee. Some of the views expressed 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.

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]

[X] manufacturer did not respond to request for data

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.