NEW DRUGS

Elasomeran/imelasomeran

Approved indication: prevention of COVID-19

Spikevax bivalent original/Omicron (Moderna) multi-dose vials containing 0.1 mg/mL

Vaccines against SARS-CoV-2 became available during 2021. However, in November 2021 the Omicron variant of the virus emerged and became the dominant strain. Several sub-lineages of the Omicron variant subsequently appeared. The vaccines developed earlier in the pandemic were less effective against Omicron. Vaccine manufacturers have therefore needed to develop new products to improve protection. Clinical trials are ongoing, but data have been provided to regulatory agencies to enable emergency or provisional use of the new products. The provisional approval of elasomeran/imelasomeran in Australia is for use as a booster dose in adults.

Elasomeran was the main component of a messenger RNA (mRNA) vaccine approved in 2021. Imelasomeran is also a mRNA vaccine, but is based on the spike protein of Omicron lineages. The two vaccines are enclosed in lipid nanoparticles to enable them to enter cells after intramuscular injection. Each 0.5 mL dose contains 25 micrograms of elasomeran and 25 micrograms of imelasomeran. After entry into cells the vaccines' mRNA stimulates the production of spike proteins. This generates an immune response which may prevent subsequent infection with SARS-CoV-2.

At present, the evidence for this bivalent vaccine is based on its immunogenicity in adults. One trial is studying people who have previously received two doses and a booster of elasomeran. A group of 437 adults was given the bivalent vaccine and 377 were given another dose of elasomeran as their second booster. By 29 days after these boosters, antibody titres against SARS-CoV-2 had increased in both groups. There was no difference between the bivalent vaccine and elasomeran alone in stimulating antibodies against an ancestral variant of the virus. When considering the Omicron variant, the response was greater in the group given the bivalent vaccines (geometric mean ratio 1.7).

Most people will have adverse effects to a booster of elasomeran or the bivalent vaccine. These are usually mild or moderate and resolve in a few days. Approximately 80% will have pain at the injection site. There may also be swelling at the injection site and axilla. Erythema was more frequent with the bivalent vaccine (6.9% vs 3.7%). Very common systemic effects include headache, fatigue, myalgia and arthralgia.

While the combination of elasomeran and imelasomeran produces neutralising antibodies, the effectiveness of this bivalent booster is yet to be confirmed. The ongoing study was not designed to evaluate effectiveness, but it found that after a median follow-up of 43 days, 3.2% of those given the bivalent vaccine were infected by SARS-CoV-2 compared with 1.9% of the elasomeran group after a median of 57 days. No participants needed hospital admission. While the adverse effects will probably resemble those of elasomeran, the safety data are limited in size and duration. Reporting adverse events, following a bivalent booster dose, to the Therapeutic Goods Administration is therefore particularly important.

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.

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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.