NEW DRUGS

New drugs

Andusomeran for prevention of COVID-19 disease

Approved indication: prevention of COVID-19 disease

Spikevax XBB.1.5 (Moderna)
pre-filled syringe containing one dose of 50 micrograms/0.5 mL suspension for injection

Raxtozinameran for prevention of COVID-19 disease

Approved indication: prevention of COVID-19 disease

Comirnaty Omicron XBB.1.5 (Pfizer)
multidose vials containing 6 doses of 30 micrograms/0.3 mL (for people 12 years and older) and single-dose vials containing 10 micrograms/0.3 mL (for children 5 years to younger than 12 years) suspension for injection

As the SARS-CoV-2 virus continues to evolve, the World Health Organization has made recommendations to develop vaccines to provide protection against newer variants.[1] The latest mRNA vaccines, andusomeran and raxtozinameran, are monovalent vaccines designed to protect against COVID-19 disease caused by Omicron XBB.1.5 and related emerging subvariants. At the time of writing, most infections in Australia are caused by the JN.1 subvariant (a sublineage of the Omicron BA.2.86 subvariant).[2,3]

Andusomeran and raxtozinameran may be used for primary vaccination or as an additional dose to maintain protection in those who have been previously vaccinated. The term 'booster' is often used to describe additional doses following primary vaccination, but the Therapeutic Goods Administration (TGA) Advisory Committee on Vaccines suggests this term is not useful or accurate for these vaccines. These vaccines contain a different active ingredient from the original monovalent vaccines (targeting the ancestral strain) and the bivalent mRNA vaccines (targeting Omicron BA.4-5 and the ancestral strain), and they do not 'boost' the immune response against the ancestral strain (which is no longer circulating).[4]

Andusomeran is approved for people 12 years and older as a 2-dose primary series or as an additional dose in those who have been previously vaccinated.[5] The vaccine is administered intramuscularly, preferably in the deltoid.[6]

Raxtozinameran is approved for people aged 6 months and older as a 2-dose primary series or as an additional dose in those who have been previously vaccinated.[7] However, at the time of writing, a formulation for children aged 6 months to younger than 5 years is not available in Australia. As the volume of each dose is only 0.3 mL, it is important to use a low dead-volume syringe when preparing the intramuscular injection. The vaccine is administered intramuscularly, preferably in the deltoid.[6]

The efficacy and safety of the monovalent XBB.1.5 mRNA vaccines has largely been inferred from extensive clinical studies and real-world experience with earlier COVID-19 vaccines;[4,6,8] however, direct data are also available, including preclinical studies and limited immunogenicity, safety and effectiveness data.[9-13] The risk of myocarditis and pericarditis with the monovalent XBB.1.5 mRNA vaccines is currently unclear. Long-term safety data are not available for either of the vaccines.

Andusomeran has been studied in an ongoing phase 2/3 open-label study. Participants (n=101 adults) were randomised to receive 50 micrograms of andusomeran alone, or an investigational bivalent vaccine containing 25 micrograms andusomeran plus 25 micrograms Omicron BA.4-5 spike proteins.[9] The vaccines were administered as a fifth dose to people who had previously received a primary series plus additional doses of mRNA COVID-19 vaccines. The median interval between the fourth and the fifth doses was approximately 8 months in both groups. Both the monovalent XBB.1.5 vaccine and the investigational bivalent vaccine elicited potent neutralising antibody responses against all variants evaluated when tested 15 days after administration (XBB subvariants: XBB.1.5, XBB.1.6, XBB.2.3.2, EG.5.1, FL.1.5.1; as well as the BA.4-5, BQ.1.1 and BA.2.86 subvariants). The immunogenicity was not compared between the 2 randomised groups. The rate and types of adverse reactions seen were similar to those reported for elasomeran (the Moderna original) and elasomeran+davesomeran bivalent mRNA COVID-19 vaccines; common reactions included injection-site reactions, headache, fatigue, myalgia and arthralgia.

Raxtozinameran has been studied in an ongoing phase 2/3 study. Participants (n=412 people

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The new drug commentaries in *Australian Prescriber* are prepared by the editors and reviewed 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.

aged 12 years or older) were vaccinated with raxtozinameran 30 micrograms after at least 3 previous doses of a COVID-19 mRNA vaccine, with the most recent dose being an Omicron BA.4-5 bivalent vaccine at least 150 days before study vaccination. Immunogenicity was evaluated in a subset of 37 participants aged 18 years or older. The raxtozinameran vaccine produced higher neutralising titres against Omicron XBB.1.5, EG.5.1 and BA.2.86 than a matched group who received an Omicron BA.4-5-adapted vaccine at 7 days, and produced robust neutralising antibody responses to all 3 subvariants at 1 month. Common adverse reactions were injection-site reactions, fatigue, headache, chills, myalgia and arthralgia, and diarrhoea.[10]

Early short-term epidemiological and observational data on vaccine effectiveness of the monovalent XBB.1.5 mRNA vaccines (both andusomeran and raxtozinameran) from cohorts in Denmark, the Netherlands and the United States indicate that they provide protection against symptomatic infection, hospitalisation and severe disease associated with current circulating variants of COVID-19, including the JN.1 subvariant.[11-13]

In November 2023 the Australian Technical Advisory Group on Immunisation (ATAGI) recommended that the monovalent XBB.1.5 vaccines are preferred over other vaccines for use in children aged 5 years and older and adults who are currently recommended primary or additional doses of COVID-19 vaccine.[6] For further information, including vaccine eligibility, timing and dosage, see the *Australian Immunisation Handbook*.

This new drug comment was finalised on 29 February 2024.

T T manufacturer provided additional useful information. 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 these drugs 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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