(Medsafe, 2024a) [30 Apr 2024]

COVID-19

Revised: 9 July 2024

Approval status of COVID-19 vaccines applications received by Medsafe

A Medsafe approval is one step in the process for accessing a COVID-19 vaccine. Once approved, the New Zealand Government then considers advice and makes decisions on when and for who a particular vaccine will be used as part of the COVID-19 immunisation programme. For more information, please go to the Ministry of Health website www.health.govt.nz or see a description of the Medsafe approval process for COVID-19 vaccines.

Comirnaty (COVID-19 mRNA vaccine) (Pfizer-BioNTech): 12 years and older
Concentrate for injection 30 µg/0.3 mL (purple cap, must dilute)

Status
Full approval under section 20 of the Medicines Act on 15 November 2023

Approved indication
Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV2, in individuals 12 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

Documents

- Gazette notice
- Data Sheet (PDF, 22 pages, 596 KB)
- Consumer Medicine Information (PDF, 4 pages, 82 KB)
- Risk Management Plan update 29 May 2024 (PDF 199 KB, 8 pages)

Risk management plans (RMPs) set out the known safety information for a medicine and measures to monitor the safety of the medicine. RMPs include a summary of the known safety profile and risks, activities to minimise the risks, and plans to gain more information on the medicine.

See also: mRNA Vaccines

Comirnaty (Pfizer-BioNTech): 5 years and older
Solution for injection 30 µg/0.3 mL (grey cap, do not dilute)
Concentrate for injection 10 µg/0.2 mL (orange cap, must dilute)

Status
Full approval under section 20 of the Medicines Act on 15 November 2023

Approved indications

Solution for injection 30 µg/0.3 mL (grey cap, do not dilute)
Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV2, in individuals 12 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

Concentrate for injection 10 µg/0.2 mL (orange cap, must dilute)
Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV2, in individuals 5 to 11 years of age.

The use of this vaccine should be in accordance with official recommendations.

Documents

- Gazette Notice
- Data sheet (12 years of age and older) (PDF, 24 pages, 513 KB)
- Consumer Medicine Information (12 years of age and older) (PDF, 4 pages, 156 KB)
- Data sheet (5 to 11 years of age) (PDF, 26 pages, 550 KB)
- Consumer Medicine Information (5 to 11 years of age) (PDF, 4 pages, 152 KB)
- Dear Healthcare Professional Letter (PDF, 2 pages, 813 KB)
- Risk Management Plan update 29 May 2024 (PDF 199 KB, 8 pages)

Comirnaty (Pfizer-BioNTech): 6 months to 4 years
Solution for injection 3 µg/0.2 mL (maroon cap, must dilute)

Status
Full approval under section 20 of the Medicines Act on 15 November 2023

Approved indication
Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in infants and children aged 6 months to 4 years.

Documents

- Gazette Notice
- Risk Management Plan update 29 May 2024 (PDF 199 KB, 8 pages)

Comirnaty Original/Omicron BA.1 (Pfizer-BioNTech): 12 years and older
Solution for injection 15/15 µg/0.3 mL

Approval pathway
New medicine application

Status
Provisional approval renewed under section 23 of the Medicines Act with conditions on 2 November 2023, valid until 3 November 2025.

Approved indication
A booster dose for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 12 years of age and older who have previously received at least a primary vaccination course against COVID-19.

The use of this vaccine should be in accordance with official recommendations.

Documents

- Gazette Notice
- Risk Management Plan update 29 May 2024 (PDF 199 KB, 8 pages)

Comirnaty Original/Omicron BA.4/5 (Pfizer-BioNTech): 12 years and older
Solution for injection 15/15 µg/0.3 mL

Status
Provisional approval renewed under section 23 of the Medicines Act with conditions on 2 November 2023, valid until 3 November 2025.

Approved indication
A booster dose for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 12 years of age and older who have previously received at least a primary vaccination course against COVID-19.

The use of this vaccine should be in accordance with official recommendations.

Documents

- Gazette Notice
- Risk Management Plan update 29 May 2024 (PDF 199 KB, 8 pages)

Comirnaty XBB 1.5 (Pfizer-BioNTech)

Solution for injection, 30mcg/0.3mL dose, SDV (light grey, do not dilute)
Solution for injection 30mcg/0.3mL dose, MDV (dark grey, do not dilute)

Status
Full approval under section 20 of the Medicines Act on 20 December 2023

Approved indication
Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 12 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

Documents

- Gazette notice
- Datasheet (light and dark grey) (PDF 598 KB, 23 pages)
- Consumer Medicine Information (PDF 194KB, 4 pages)
- Risk Management Plan update 29 May 2024 (PDF 199 KB, 8 pages)

Concentrate for injection 3mcg/0.2mL, MDV (maroon cap, must dilute)
Concentrate for injection 10 mcg/0.2 mL dose, MDV (orange cap, must dilute)
Concentrate for injection, 3mcg/0.3mL, MDV (yellow cap, must dilute)
Solution for injection, 10mcg/0.3mL dose, SDV (light blue, do not dilute)
Solution for injection, 10 mcg/0.3mL dose, MDV (dark blue, do not dilute)

Status
Application received for approval under section 20 of the Medicines Act on 16 November 2023

Proposed indication
Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals aged 6 months and older.

The use of this vaccine should be in accordance with official recommendations.

COVID-19 Vaccine Janssen
Suspension for injection $5x10^{10}$ VP/0.5 mL

Status
Provisional approval renewed under 23(4) of the Medicines Act with conditions on 6 April 2022, valid until 7 April 2024

Approved indication
Active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

Documents

- Gazette notice
- Data Sheet (PDF, 15 pages, 420 KB)
- Consumer Medicine Information (PDF, 4 pages, 178 KB)
- Risk Management Plan (PDF, 10 pages, 151 KB)

See also: Viral Vector Vaccines

Vaxzevria (AstraZeneca)
Solution for injection 5 x 10^{10} VP/0.5 mL

Status
Provisional approval renewed under 23(4) of the Medicines Act with conditions on 28 April 2022, valid until 29 April 2024.

Approved indication
Active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

Documents

- Gazette notice
- Data Sheet (PDF, 15 pages, 160 KB)
- Consumer Medicine Information (PDF, 5 pages, 126 KB)
- Dear Healthcare Professional Letter (PDF, 3 pages, 215 KB)
- Risk Management Plan (PDF 14 pages, 304 KB)

See also: Viral Vector Vaccines

Nuvaxovid (Novavax)
Solution for injection, 5 µg/0.5 mL

Status
Provisional approval granted under section 23 of the Medicines Act with conditions on 4 November 2024.

Approved indication
Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in individuals 12 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

Documents

- Gazette notice
- Data sheet (PDF 12 pages, 354 KB)
- Consumer Medicine Information (PDF 4 pages, 240 KB)
- Dear Healthcare Professional Letter (PDF 1 page, 222 KB)
- Risk Management Plan (PDF 7 pages, 260 KB)

Nuvaxovid XBB 1.5 (Novavax)
Solution for injection, 5 µg/0.5 mL

Status
Application withdrawn by sponsor on 3 July 2024

Proposed indication
Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in individuals 12 years of age and older.

Spikevax (Moderna)
Suspension for injection 0.2 mg/0.5 mL

Status
Provisional approval granted under section 23 of the Medicines Act with conditions on 17 June 2022.

Approved indication
Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in individuals 12 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

Documents

- Gazette notice