MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

(Medsafe, 2022)
[21 Dec 2021]; [1 Mar 2022]; [14 Apr 2022]

COVID-19

Approval status of COVID-19 treatment applications received by Medsafe

A Medsafe approval is one step in the process for accessing a COVID-19 treatment. In addition to Medsafe assessment of applications for regulatory approval, PHARMAC is working with pharmaceutical companies to negotiate supply for New Zealand patients. For more information, please see the website Ministry of Health and PHARMAC websites or see a description of the Medsafe approval process for COVID-19 treatments. More information about medicine applications and approvals can also be found using our Product/Application Search.

Dexmethsone
Ronapreve (casirivimab and imdevimab)
Veklury (remdesivir)
Paxlovid (nirmatrelvir and ritonavir)
Lagevrio (molnupiravir)
Actemra (tocilizumab)
Evusheld (tixagevimab)

Dexmethsone
Dexamethasone 0.3 mg tablet
Healthcare Logistics

Status
Extension of indications to include treatment of severe COVID-19 approved under section 24 of the Medicines Act 1981 on 16 November 2020.

Approved indication
Dexamethasone is indicated in the treatment of coronavirus disease 2019 (COVID-19) in adult and adolescent patients (aged 12 years and older with body weight at least 40 kg) who require supplemental oxygen therapy.

Documents

- Data Sheet

Ronapreve
Casirivimab/imdevimab 120 mg/mL solution for injection
Roche Products (NZ) Ltd

Approval pathway
New medicine application

Status
Approved under section 20 of the Medicines Act on 21 December 2021

Approved indications

Treatment
Treatment Ronapreve is indicated for the treatment of COVID-19 in adults and adolescents (aged 12 years and older and weighing at least 40 kg) who do not require supplemental oxygen for COVID-19 and who are at increased risk of progressing to severe COVID-19.

Post-exposure prophylaxis
Ronapreve is indicated for the prevention of COVID-19 in adults and adolescents (aged 12 years and older and weighing at least 40 kg) who have been exposed to SARS-CoV-2 AND who either:

- have a medical condition making them unlikely to respond to or be protected by vaccination, or
- are not vaccinated against COVID-19.

Ronapreve is not intended to be used as a substitute for vaccination against COVID-19.

Documents

- Datasheet
- CMI
- Gazette Notice
- Dear Healthcare Professional Letter - 24 December 2020
- Dear Healthcare Professional Letter - 31 January 2021

Veklury
Remdesivir 100 mg powder for injection
Gilead Sciences (NZ)

Approval pathway
Abbreviated new medicine application

Status
The initial assessment of this application has been completed and Medsafe is waiting to receive additional information from the sponsor.

Proposed indication
Veklury is indicated for the treatment of coronavirus disease 2019 (COVID-19) in adults and adolescents (aged 12 years and older weighing at least 40 kg) with pneumonia, requiring supplemental oxygen.

Paxlovid
NIrmatrelvir 150 mg film coated tablet + ritonavir 100 mg film coated tablet
Pfizer New Zealand Limited

Approval pathway
Rolling new medicine application

Status
Approved under section 23 of the Medicines Act with conditions on 2 March 2022.

Approved indications
Treatment of coronavirus disease 2019 (COVID-19) in adults 18 years of age and older, who do not require initiation of supplemental oxygen due to COVID-19 and are at increased risk of progression to hospitalisation or death.

Documents

- Gazette Notice
- Datasheet
- CMI
- Risk Management Plan
- Dear Healthcare Professional Letter - 5 April 2022

Lagevrio
Molnupiravir 200 mg capsule
Merck Sharp & Dohme (New Zealand) Limited

Approval pathway
Abbreviated New Medicines Application

Status
Approved under section 23 of the Medicines Act with conditions on 14 April 2022

Proposed indications
Lagevrio is indicated for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults aged 18 years and older who are at increased risk of progressing to severe COVID-19, hospitalisation or death.

Documents

- Gazette Notice (PDF 37 KB, 1 page)
- Risk Management Plan (PDF 128 KB, 2 pages)
- Data Sheet (PDF 486 KB, 16 pages)
- Consumer Medicine Information (PDF 185 KB, 4 pages)
- Dear Healthcare Professional Letter (412 KB, 4 pages)

Actemra
Tocilizumab 20 mg/mL concentrate for infusion

Roche Products (NZ) Ltd

Approval pathway
Changed Medicine Notification Status Application received 16 March 2022, initial evaluation underway.

Proposed indications
Actemra is indicated for the treatment of coronavirus disease 2019 (COVID-19) in hospitalised adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation.

Evusheld
Tixagevimab 100 mg/mL Solution for injection
AstraZeneca

Approval pathway
Abbreviated new medicine application

Status
The sponsor has provided additional information upon request from Medsafe, which is currently under assessment.

Proposed indication
Pre-exposure prophylaxis of COVID-19 in adults and adolescents aged 12 years and older weighing at least 40 kg