Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	374310	RONAPREVE casirivimab 120mg/ml and imdevimab 120mg/ml solutions for infusion or injection in 1332 mg multi dose vials

ARTG entry for	Medicine Registered (Provisional)
Sponsor	Roche Products Pty Ltd
Postal Address	30-34 Hickson Road, Sydney, NSW, 2000 Australia
ARTG Start Date	18/10/2021
Product Category	Medicine
Status	Active
Approval Area	Drug Safety Evaluation Branch

Medicine under additional monitoring

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1 . RONAPREVE casirivimab 120mg/ml and imdevimab 120mg/ml solutions for infusion or injection in 1332 mg multi dose vials

Product Type	Single Medicine Product	**Effective Date**	18/10/2021

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Provisionally Registered Indications

Ronapreve has provisional approval for the indications below: 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. (refer to section 4.2 Dose and method of administration and section 5.1, Clinical Trials)
Ronapreve is not intended to be used as a substitute for vaccination against COVID-19. The decision has been made on the basis of short term efficacy and safety data. Continued approval of this indication depends on the evidence of longer term efficacy and safety from ongoing clinical trials and post-market assessment.

Provisionally Registered Conditions

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

This product is included in the Black Triangle Scheme

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Glass Type I Clear	12 Months	Store at 2 to 8 degrees Celsius	Not recorded	Do not Shake Do not Freeze Protect from Light

Public Summary

Pack Size/Poison information

Pack Size	Poison Schedule
20 mL multidose vials	(S4) Prescription Only Medicine

Components

1 . imdevimab

Dosage Form	Injection, solution
Route of Administration	Intravenous Infusion Subcutaneous
Visual Identification	20 ml glass vial containing clear to slightly opalescent and colourless to pale yellow solution.

Active Ingredients

imdevimab	**120 mg/mL**

Other Ingredients (Excipients)

histidine hydrochloride monohydrate
histidine
polysorbate 80
sucrose
water for injections

2 . casirivimab

Dosage Form	Injection, solution
Route of Administration	Subcutaneous Intravenous Infusion
Visual Identification	20 ml glass vial containing clear to slightly opalescent and colourless to pale yellow solution.

Active Ingredients

casirivimab	**120 mg/mL**

Other Ingredients (Excipients)

histidine hydrochloride monohydrate
histidine
polysorbate 80
sucrose
water for injections