24 December 2021

Ronapreve® casirivimab 120 mg/mL and imdevimab 120 mg/mL, injection solution: Important information about Ronapreve supplied in New Zealand

To Whom it May Concern,

Roche Products (New Zealand) Limited would like to inform you that in order to support supply of Ronapreve in New Zealand during the COVID-19 pandemic, Medsafe has granted its consent permitting Roche to supply certain batches of product with carton and vial label artwork and a package insert differing to the registered by Medsafe. This product is labelled '*Casirivimab 120 mg/mL and Imdevimab 120 mg/mL Concentrates for Solution for Infusion*'.

Healthcare professionals must be aware of the approved conditions for Ronapreve® when administering '*Casirivimab 120 mg/mL and Imdevimab 120 mg/mL Concentrates for Solution for Infusion*'. Please review the latest Medsafe approved Data Sheet available via:
https://www.medsafe.govt.nz/Medicines/infoSearch.asp

Summary

- The label on the supplied cartons '**Casirivimab and Imdevimab 120 mg/ml Concentrate for Solution for Infusion**' is different from the Medsafe approved label '**Ronapreve 120 mg/ml Solution for Injection or Infusion'**
- The Medsafe approved route of administration is via **intravenous infusion** or **subcutaneous injection**. The carton, labels and package insert of Casirivimab and Imdevimab only details intravenous infusion
- The package insert of Casirivimab and Imdevimab supplied in the pack only includes information regarding the use for the treatment of COVID-19. Medsafe has granted approval for the use of Ronapreve in New Zealand for the **treatment** and **prevention of COVID-19 (refer Table 1)**

The information contained within this letter applies to all cartons labelled '**Casirivimab and Imdevimab 120 mg/ml Concentrate for Solution for Infusion**' used in New Zealand. It is currently not known how long this stock is expected to be on the New Zealand market before Medsafe approved stock is supplied. Please read and cascade as appropriate the information contained in this letter to ensure awareness of the differences between this product and Medsafe approved Ronapreve and an understanding of the registered indications and prescribing information.

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Key information

Table 1 summarises the differences in key elements of product supplied and the Medsafe registered product

Item	**Supplied Casirivimab and Imdevimab**	**Medsafe registered Ronapreve** https://www.medsafe.govt.nz/Medicines/infoSearch.asp
Name on the carton	Casirivimab and imdevimab 120 mg/mL	Ronapreve® Casirivimab 120 mg/mL and imdevimab 120 mg/mL
Route of administration	Intravenous infusion	Intravenous infusion or subcutaneous injection
Indication	Casirivimab and imdevimab are medicines for the treatment of confirmed COVID-19 in patients aged 12 years and older that do not require supplemental oxygen for COVID-19 and who are at high risk of progressing to severe COVID-19.	**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.
Dose	• 1.2 g (600mg casirivimab and 600mg imdevimab) as a once off dose for treatment of COVID-19	• **Treatment:** 1.2 g (600mg casirivimab and 600mg imdevimab) as a once off dose • **Post-exposure prophylaxis:** 1.2 g (600mg casirivimab and 600mg imdevimab) as a once off dose • **Ongoing prophylaxis:** 1.2 g (600mg casirivimab and 600mg imdevimab) as a loading dose and 0.6 g subsequent doses (300mg casirivimab and 300mg imdevimab) every 4 weeks
In use storage conditions	**Multi-Dose Vial (20 ml) (after initial puncture)** - 16 hours at room temperature up to 25°C - 48 hours at 2–8°C **Prepared IV Bag** - 4 hours at room temperature up to 25°C - 36 hours at 2–8°C	**Multi-Dose Vial (20 ml) (after initial puncture)** - 16 hours at room temperature up to 25°C - 48 hours at 2–8°C **Prepared IV Bag** - 12 hours at room temperature up to 25°C - 48 hours at 2–8°C **Prepared syringes** - 6 hours at room temperature up to 25°C - 24 hours at 2–8°C

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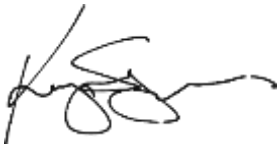
Before prescribing, please review the full Data Sheet available on Medsafe's website www.medsafe.govt.nz

Further Information
If you have any questions or require additional information regarding the use of Ronapreve (casirivimab and imdevimab) please contact Roche Medical Information by telephone on 0800 276 243 or auckland.medinfonz@roche.com

Roche product vigilance
Roche will continue to monitor the safety of Ronapreve (casirivimab and imdevimab) through established reporting mechanisms and notify regulatory authorities as per current regulations. You can assist us in monitoring the safety of Ronapreve by reporting adverse events via email to nz.drugsafety@roche.com and product compliants to nz.quality@roche.com. Alternatively, this information may be reported to the Centre for Adverse Reactions Monitoring (CARM) in Dunedin by telephone on (03) 479 7247, by fax on (03) 479 7150, online at https://nzphvc.otago.ac.nz/reporting or by email to nzphvc@otago.ac.nz.

Yours sincerely,
Roche Products (New Zealand) Limited



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Please review Product Information before prescribing, available at
https://www.medsafe.govt.nz/Medicines/infoSearch.asp