Date: January 2022

Ref: M-GB-00006105

Direct Healthcare Professional Communication

▼Ronapreve® (casirivimab and imdevimab) 120 mg/ml solution for injection or infusion: Important information for healthcare professionals about the expiry date of the 6 ml vial packs

Dear Healthcare Professional,

Roche Products Ltd would like to inform you that **an additional Batch Specific Variation (BSV) to extend the expiry date of cartons of 6 ml vials** of 'casirivimab and imdevimab 120 mg/ml Concentrate for Solution for Infusion' has been approved by the Medicines and Healthcare products Regulatory Agency (MHRA).

This letter supersedes the communication dated December 2021 (reference M-GB-00005735) at https://www.medicines.org.uk/emc/product/12863

Please read the complete information in this letter and ensure it is cascaded to the relevant teams to ensure they are using the authorised conditions. There have been no changes to the authorised indications (see Table 2 overleaf) or in-use storage conditions (Table 3) for cartons of 6 ml vials of casirivimab and imdevimab 120 mg/ml Concentrate for Solution for Infusion, these have been included for completeness.

Summary

- **The MHRA has approved a further five months extension of the expiry date of casirivimab and imdevimab 120 mg/ml Concentrate for Solution for Infusion, 300mg in 2.5ml vials, for the specified batches detailed below.**
- **This letter contains information on the expiry dates of 300mg in 2.5ml solution (in 6 ml vials) (see Table 1). Disregard expiry dates printed on the cartons and vials and the expiry date on the letter supplied with the carton:**

The stock will now expire on 30th June 2022.

- **Please be aware that 6 ml refers to the size of the vials and NOT the volume of the contents. The 6 ml vials contain 2.5 ml of solution.**

1. BSV approved batches

Table 1 details the batch numbers of the affected cartons of 6 ml vials of casirivimab and imdevimab 120 mg/ml Concentrate for Solution for Infusion

	Batch number	Expiry date stated on Vial/Carton	Previous MHRA approved Expiry date	Updated MHRA approved Expiry date
CASIRIVIMAB/IMDEVIMAB 300MG/2.5ML	N7561B01 N7561B02	12.2022	31.01.2022	30.06.2022

2. Key information to be followed within Conditional Marketing Authorisation

Table 2 summarises the key elements of the authorisation for Ronapreve Solution for Infusion or Injection.

Item	MHRA Conditional Marketing Authorisation for Ronapreve
Indication	• Treatment of acute COVID-19 infection • Prevention of acute COVID-19 infection Ronapreve is not intended to be used as a substitute for vaccination against COVID-19
Dose	• 1.2 g dose (600mg casirivimab and 600mg imdevimab) for treatment • 1.2 g dose (600mg casirivimab and 600mg imdevimab) for initial prevention • 0.6 g dose (300mg casirivimab and 300mg imdevimab) for maintenance of prevention
Route of Administration	Intravenous & Subcutaneous

3. In use storage conditions

Table 3 summarises the in use storage times to be followed as per MHRA authorisation

Item	MHRA Conditional Marketing Authorisation for Ronapreve
Prepared IV Bag	- 6 hours at room temperature (≤ 25°C) - 24 hours at 2–8°C
Prepared syringes	- 4 hours at room temperature (≤ 25°C) - 24 hours at 2–8°C

Call for reporting

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. Suspected adverse drug reactions should be reported to the MHRA through the Yellow Card scheme.

Report suspected side effects to medicines, vaccines, medical device and test kit incidents used in coronavirus testing and treatment to the Coronavirus Yellow Card reporting site https://coronavirus-yellowcard.mhra.gov.uk/.

Adverse events should also be reported to Roche Products Ltd. Please contact Roche Drug Safety Centre by emailing welwyn.uk_dsc@roche.com or calling +44 (0)1707 367554.

As Ronapreve is a biological medicine, healthcare professionals should report adverse reactions by brand name and batch number. When reporting please provide as much information as possible, including information about medical history, any concomitant medications, onset, treatment dates, and product brand name and batch number.

Thank you in advance for your cooperation with this additional information.
Yours faithfully,

Dr Marius Scholtz
Chief Medical Officer, Roche Products Limited