Casirivimab and Imdevimab (also known as REGEN-COVTM) Co-Packaged Product Quick Reference Guide

Information for Temporary Alternative Packaging of REGEN-COV under Emergency Use Authorization (EUA)

Scan the QR code or go to www.REGENCOV.com for the FDA-authorized Fact Sheets (one for the Healthcare Provider and one for the Patient/Caregiver) for current product information for casirivimab and imdevimab.



It is important to note:

- Each co-packaged carton contains individual antibody solutions in separate vials as follows:
 - o **One** (1) vial containing casirivimab; 300 mg/2.5 mL (120 mg/mL) or 1,332 mg/11.1 mL (120 mg/mL)
 - o **One (1)** vial containing imdevimab; 300 mg/2.5 mL (120 mg/mL) or 1,332 mg/11.1 mL (120 mg/mL)
 - One (1) package leaflet which is not approved for use in the US. This leaflet should be discarded. Please refer to the authorized EUA Fact Sheets only (scan the QR code above).
- The carton is labeled as "casirivimab and imdevimab 120 mg/mL concentrate for solution for infusion". Do not confuse this co-packaged carton with REGEN-COV (casirivimab and imdevimab) co-formulated solution.
- The vials in the co-packaged carton may be used to prepare and administer intravenous infusions as well as subcutaneous injections despite having the statements such as "Concentrate for solution for infusion" or "For intravenous infusion after dilution".
- Carton and vial labels do not include an NDC. Use the NDC listed below based on the package.

Co-Packaged Carton Contents	Co-Packaged Components	Concentration	Co-Packaged Carton NDC Number
2 Vials	1 vial of casirivimab (NDC 61755-024-00)	1,332 mg/11.1 mL (120 mg/mL)	61755-042-02
	1 vial of imdevimab (NDC 61755-025-00)	1,332 mg/11.1 mL (120 mg/mL)	
2 Vials	1 vial of casirivimab (NDC 61755-026-00)	300 mg/2.5 mL (120 mg/mL)	61755-045-02
	1 vial of imdevimab (NDC 61755-027-00)	300 mg/2.5 mL (120 mg/mL)	

- The barcode on the co-packaged carton label may not register with U.S. scanning systems. Confirm that the barcode provides correct information when scanned and if not, consider manually inputting the product specific information into electronic systems. There is no barcode on the co-packaged vial.
- Roche manufactures the co-packaged product on behalf of Regeneron and is listed on the package.
- Refer to the "Dear Healthcare Provider Letter" for additional information on the co-packaged product.

Health care providers must submit a report on <u>ALL MEDICATION ERRORS</u> and <u>ALL SERIOUS ADVERSE</u> <u>EVENTS</u> potentially related to REGEN-COV (casirivimab and imdevimab). See the FDA Fact Sheet for Health Care Providers (Sections 8 and 9 of the Full EUA Prescribing Information) for reporting instructions.

If you have questions, please contact Regeneron at 1-844-734-6643.

REGENERON

Manufactured for: Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, NY 10591-6707 ©2021 Regeneron Pharmaceuticals, Inc. All rights reserved.