

IMPORTANT PRESCRIBING INFORMATION

Subject: Minimizing medication errors with REGEN-COV® (casirivimab and imdevimab)

Dear Healthcare Provider:

The purpose of this notice is to make you aware of medication errors associated with the three presentations of REGEN-COV® (casirivimab and imdevimab) that are currently in distribution under the FDA's Emergency Use Authorization (EUA) program: (1) co-formulated product in a single vial; (2) Roche co-packaged carton with one vial of casirivimab and one vial of imdevimab; and (3) dose pack bag with individual vials of casirivimab and imdevimab. To minimize medication errors during dose preparation and administration, it is important to note which presentation is being used ([Table 1](#)).

Regeneron and FDA have received reports of medication errors that have occurred when preparing and administering REGEN-COV. The medication error reports include:

- Wrong dose errors (e.g., 1,200 mg of casirivimab and 1,200 mg of imdevimab administered instead of the prescribed dose of 600 mg casirivimab and 600 mg imdevimab dose)
- Administration of a single antibody instead of administering both casirivimab and imdevimab together
- Incorrect administration errors (e.g., incorrect infusion rate, confusion with the number of vials and injection sites when given subcutaneously)

Resources clarifying the dose preparation and administration can be found on www.REGENCOV.com and include:


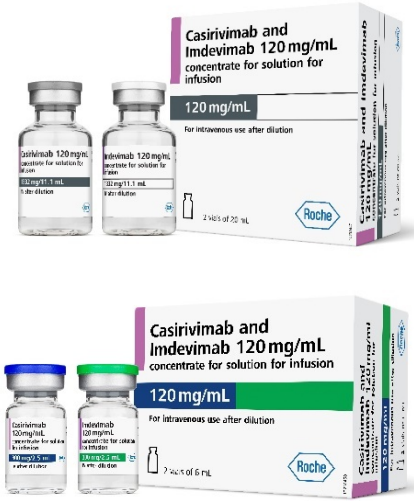

- Images of all presentations (located on three separate tabs, down the page) <https://www.regencov.com/hcp/dosing/packaging>
- Instructions on dose preparation for IV or subcutaneous injection by packaging presentation <https://www.regencov.com/hcp/dosing/dosing-administration>
- Vignettes on dose preparation and administration <https://www.regencov.com/hcp/resources>

Previous Changes in Authorized Dosing and Administration Information

The authorized dosing and administration of REGEN-COV has changed since its initial authorization on November 21, 2020. It is important to refer to the current EUA Healthcare Provider [\(HCP\) Fact Sheet](#) for the most accurate information as EUA labeling information in your possession and in distribution may no longer be current and could change over time based on updated product information and new safety or efficacy data. For some of the presentations, the vials in the pack can be used to prepare more than one dose according to the specific instructions in the FDA-authorized EUA HCP Fact Sheet.

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Table 1: REGEN-COV (casirivimab and imdevimab) Packaging Presentations

Presentation	Image	Contents
<p>Carton with Co-formulated Product in a Single Vial</p>		<p>Carton with one 10 mL vial containing 600 mg of casirivimab and 600 mg of imdevimab</p> <p>Each mL contains 60 mg of casirivimab and 60 mg of imdevimab</p>
<p>Roche Co-packaged Carton with 1 Vial of Casirivimab and 1 Vial of Imdevimab^a</p>		<p>Two carton configurations:</p> <p>Carton co-packaged with</p> <ul style="list-style-type: none"> • 11.1 mL vial containing 1,332 mg of casirivimab (120 mg/mL) and • 11.1 mL vial containing 1,332 mg of imdevimab (120 mg/mL) <p>Carton co-packaged with</p> <ul style="list-style-type: none"> • 2.5 mL vial containing 300 mg of casirivimab (120 mg/mL) and • 2.5 mL vial containing 300 mg of imdevimab (120 mg/mL)
<p>Dose Pack Bag with Individual Vials of Casirivimab and Imdevimab</p>		<p>Each dose pack bag contains individual vials of casirivimab and imdevimab in varying configurations (either 2, 5, or 8 cartons) such that a total of 1,200 mg of casirivimab and 1,200 mg of imdevimab is available for use.</p> <p>The dose pack bag containing 2 cartons has 1 vial of 1,332 mg of casirivimab and 1 vial of 1,332 mg of imdevimab.</p> <p>The dose pack bag containing 5 cartons has 1 vial of 1,332 mg of casirivimab and 4 vials of 300 mg of imdevimab or 4 vials of 300 mg of casirivimab and 1 vial of 1,332 mg of imdevimab.</p>

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		<p>The dose pack bag containing 8 cartons has 4 vials of 300 mg of imdevimab and 4 vials of 300 mg of casirivimab.</p> <p>Each mL contains casirivimab 120 mg/mL or imdevimab 120 mg/mL</p> <p>Each dose pack includes a one-page informational document.^b</p>
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^a The co-packaged cartons were manufactured by Regeneron's development partner Roche Pharmaceuticals and are being distributed by Regeneron, to increase the available doses of casirivimab and imdevimab.

^b The one-page informational document contains inaccurate dosing information as per the current HCP fact sheet. The QR code on the document can be used to obtain the most current HCP Fact Sheet.

HEALTHCARE PROVIDER ACTION

- **Information about the use of REGEN-COV may change over time.** Stay current with the latest Fact Sheet for Health Care Providers (<https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-hcp.pdf>).
- All formulations and presentations of REGEN-COV can be used to prepare treatment or post-exposure prophylaxis doses for intravenous infusion or subcutaneous injection.
- Due to multiple presentations of REGEN-COV, it is important to educate staff on identifying the presentations and preparing doses accurately with each presentation at your site. Online resources are available at www.REGENCOV.com.
- Store REGEN-COV in the refrigerator in the original carton or bag. Do not open cartons or dose pack bag until the time at which the intravenous infusion or the subcutaneous injections will be prepared.
- Do not comingle REGEN-COV presentations. Exercise caution to differentiate the co-formulated carton (containing a single vial of co-formulated product) from the Roche co-packaged carton (containing individual vials of casirivimab and imdevimab).
- Healthcare providers should ensure their Electronic Health Records (EHRs) have all product information in the system to allow for the use of the three presentations to prepare doses for intravenous infusion or subcutaneous injection for treatment or post-exposure prophylaxis. Create alerts to remind providers that:
 - if preparing an intravenous infusion, casirivimab and imdevimab must be administered together after dilution.

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- for intravenous infusion, update infusion system library with current infusion rate information and reminders to use in-line or add-on filter during administration.
- if preparing subcutaneous injections, label the individual syringes to ensure the patient receives all syringes comprising a single dose. The syringes must be administered consecutively, each at a different injection site as instructed in the HCP Fact Sheet.
- Specific considerations for Roche co-packaged carton:
 - The barcode on the co-packaged carton label may not register with U.S. scanning systems and does not include NDCs on the carton. There is no barcode on the co-packaged vial labels. Institutions should manually input the product information into their systems to confirm the barcode systems do not provide incorrect information when the product is scanned. Alternative procedures, including checking the label information manually and/or applying site-generated barcodes, should be instituted to assure that the correct drug product is being used for dose preparation.
- Specific considerations for dose pack bags:
 - The informational document in the plastic bag should be discarded as it contains outdated information. Refer to the current EUA [HCP Fact Sheet](#).
 - The label on the dose pack bag is incorrect. It states that the bag includes one complete treatment dose of REGEN-COV. However, the dose pack bags contain enough product to prepare more than one dose, depending on the authorized use.

Reporting Adverse Events and Medication Errors

Under the EUA, all serious adverse events and all medication errors potentially related to casirivimab and imdevimab must be reported within 7 calendar days from the onset of the event. Serious adverse event reports and medication error reports should be submitted to FDA's MedWatch program using one of the following methods:

- Complete and submit the report online: www.fda.gov/medwatch/report.htm, or
- Complete and submit a postage-paid Form FDA 3500 (<https://www.fda.gov/media/76299/download>) and return by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 208529787, or by fax (1-800-FDA-0178), or
- Call 1-800-FDA-1088 to request a reporting form.

Please provide a copy of all FDA MedWatch forms to Regeneron via fax (1-888-876-2736) or email (medical.information@regeneron.com).

Healthcare providers should direct questions about REGEN-COV (casirivimab with imdevimab) packaging or use to the Regeneron Medical Information Department at 1-844-734-6643 or to medical.information@regeneron.com.

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The EUA Fact Sheet for Healthcare Providers is included with this notice, available at www.REGENCOV.com, or available by scanning the QR Code below:



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Enclosure:

EUA Fact Sheet for Healthcare Providers