IMPORTANT PRESCRIBING INFORMATION

Subject: New Name and Packaging for Regeneron COVID-19 Monoclonal Antibodies (casirivimab with imdevimab) to be administered together: REGEN-COV™

Dear Healthcare Provider:

The purpose of this notice is to make you aware of the proprietary name (REGEN-COV™) and new packaging (dose packs) for casirivimab with imdevimab.

REGEN-COV™, (casirivimab with imdevimab) to be administered together is authorized for use under an emergency use authorization (EUA) for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization. Healthcare Providers should administer REGEN-COV™ (casirivimab with imdevimab) per the full Fact Sheet for Healthcare Providers available at www.REGENCOV.com. Healthcare providers should review the enclosed Fact Sheet for instructions on dosing, preparation and administration of REGEN-COV™ (casirivimab with imdevimab).

New REGEN-COV Dose Pack

Starting on about February 15, 2021, Regeneron will start shipping dose packs, a new packaging presentation of REGEN-COV (casirivimab with imdevimab). The REGEN-COV dose pack is a plastic bag that contains cartons of casirivimab and imdevimab to make one 2,400 mg dose (1,200 mg of casirivimab and 1,200 mg of imdevimab) and a one-page informational document.

The cartons in the REGEN-COV dose pack may vary in appearance; and the number of cartons in each dose pack may vary. The REGEN-COV dose pack could contain 2, 5, or 8 cartons, each containing vials of casirivimab and imdevimab, to make a single treatment dose (see page 2 for dose pack presentations). Regardless of the carton appearance, all of the combinations of casirivimab and imdevimab found in the dose pack make up one complete treatment dose of REGEN-COV. Each dose pack will be labeled with the name REGEN-COV and the NDC based on the combination of cartons in the dose pack (see images starting on page 4).

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1 Casirivimab and imdevimab are not approved, but the U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved products casirivimab and imdevimab to be administered together for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization only for the duration of the declaration.
Labeling of Individual Cartons in REGEN-COV Dose Packs

There are three versions of casirivimab and imdevimab carton packaging, which are reproduced in the enclosure. Please note:

- Casirivimab and imdevimab may each be supplied as two different strengths: 1,332 mg/11.1 mL (120 mg/mL) single-dose vials and 300 mg/2.5 mL (120 mg/mL) single-dose vials.
- One treatment dose (2,400 mg consisting of 1,200 mg of casirivimab and 1,200 mg of imdevimab) can consist of 4 different dose pack presentations:
  - One 11.1 mL vial of casirivimab and one 11.1 mL vial of imdevimab
  - Four 2.5 mL vials of casirivimab and four 2.5 mL vials of imdevimab
  - One 11.1 mL vial of casirivimab and four 2.5 mL vials of imdevimab
  - Four 2.5 mL vials of casirivimab and one 11.1 mL vial of imdevimab
- Some vials and cartons of casirivimab and imdevimab may be instead labeled REGN10933 and REGN10987, respectively (see pages 8 and 9 below). The cartons of these vials will also have a sticker affixed that includes the nonproprietary name of the product (“casirivimab” or “imdevimab”), the product strength and NDC number, along with a linear barcode that can be scanned by healthcare facilities.

Expiration Dates

The dose packs will expire no earlier than May 31, 2022. If you are uncertain of when the products expire, you may call Regeneron Medical Information at 1-844-734-6643. Expiration dates for dose packs can be found on the packing slip within a shipment of material and reflects the earliest expiration date of the enclosed material. Cartons in the dose pack may have different lot numbers and expiration dates but none will expire any earlier than May 31, 2022.

Inventory Management

The linear barcodes on cartons, dose packs, and shipper labels are functional and can be used to obtain the NDC of either the dose pack(s) or the carton. Please ensure proper rotation of stock by utilizing current inventory. Be aware that there are 4 new NDCs assigned for the 4 different dose pack presentations of REGEN-COV (casirivimab with imdevimab) and update your systems accordingly to capture these new NDCs and the brand name, REGEN-COV.

For previously distributed EUA casirivimab and imdevimab products (not in the new dose pack presentations), the cartons have no NDCs or functional barcodes.

Healthcare Provider Action

- Stay current with the latest Fact Sheets for Health Care Providers (https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-hcp.pdf)
- Use the brand name along with the nonproprietary name in prescribing (“REGEN-COV (casirivimab with imdevimab)”)  
- Create alerts in the electronic health record (EHR) systems for healthcare providers that casirivimab and imdevimab must be administered together after dilution by intravenous infusion.
• Store REGEN-COV (casirivimab with imdevimab) dose packs in the refrigerator in the original dose pack container together and away from other COVID-19 vaccines and drug products. **Do not open dose pack until the time at which the infusion is to be compounded.**
• Store individual cartons of casirivimab and imdevimab separately from COVID-19 vaccines and other drug products.
• Have the dosing information for casirivimab and imdevimab, that visually displays the 4 possible unique vial combinations that can be used to prepare the IV solution, available to those preparing the medication.

**Reporting Adverse Events and Medication Errors**

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.

Under the EUA, all serious adverse events and 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
• Use a postage-paid Form FDA 3500 (available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf) and return by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787, 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 at medical.information@regeneron.com.

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:

![QR Code](https://example.com/qrcode)

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**Enclosure:** EUA Fact Sheet for Healthcare Providers for REGEN-COV Dose Pack
Images of the REGEN-COV 4 Dose Pack Presentations

1. 8 carton Dose Pack (4 casirivimab: 4 imdevimab)

2 The cartons in the REGEN-COV dose pack may vary in appearance, see page 8-10 for images. Regardless of the carton appearance, all of the combinations of casirivimab and imdevimab found in the dose pack make up 1 complete treatment dose of REGEN-COV.
2. **5 carton Dose Pack (1 casirivimab: 4 imdevimab)**
3. 2 carton Dose Pack (1 casirivimab: 1 imdevimab)
4. **5 carton Dose Pack (4 casirivimab: 1 imdevimab)**
Variations of the packaging and labeling of casirivimab and imdevimab

VERSION 1

1a: casirivimab (also referred to as REGN10933) – 1,332 mg/11.1 mL
(120 mg/mL solution)

1b: imdevimab (also referred to as REGN10987) – 1,332 mg/11.1 mL
(120 mg/mL solution)

VERSION 2*

2a: casirivimab (also referred to as REGN10933) – 300 mg/2.5 mL
(120 mg/mL solution)

2b: imdevimab (also referred to as REGN10987) – 300 mg/2.5 mL
(120 mg/mL solution)

*The packaging for casirivimab and imdevimab is labeled “for intravenous infusion or subcutaneous injection.” However, casirivimab and imdevimab MUST be administered by INTRAVENOUS (IV) INFUSION ONLY under the emergency use authorization.
3a: casirivimab (also referred to as REGN10933) – 300 mg/2.5 mL (120 mg/mL solution)

3b: casirivimab (also referred to as REGN10933) – 1332 mg/11.1 mL (120 mg/mL solution)
3c: imdevimab (also referred to as REGN10987) – 300 mg/2.5 mL (120 mg/mL solution)

3d: imdevimab (also referred to as REGN10987) – 1,332 mg/11.1 mL (120 mg/mL solution)