

Important information regarding packaging, labeling and storage of COVID-19 monoclonal antibody therapeutic: REGEN-COV™

PACKAGING

The REGEN-COV™ included in this week's shipment will arrive in one of two packaging configurations:

- 1) REGEN-COV™ Dose Packs (2-Vial) **or**
- 2) Casirivimab and Imdevimab Co-Pack (2 vials per carton)

REGEN-COV™ in both packaging configurations may be used to prepare and administer intravenous infusions as well as subcutaneous injections.

Details of each packaging configuration are below:

1) REGEN-COV™ Dose Packs (2-Vial)

- Each dose pack contains 1,200 mg of casirivimab [REGN10933] and 1,200 mg of imdevimab [REGN10987].
- Casirivimab and imdevimab vial labels and carton labeling may instead be labeled REGN10933 and REGN10987.
- Although the dose pack is labeled to contain one treatment dose (2,400mg), the FDA authorized a lower dose at 1,200mg.
- Thus, **each dose pack can be used to prepare two (2) doses for treatment.**
- The vials are approved for multi-use under [USP accommodations](#) made for compounding of COVID-19 therapeutics.



2) Casirivimab and Imdevimab Co-Pack Two (2) vials per carton; Two (2) cartons required for a 600mg casirivimab/600mg imdevimab dose)

- The label on the carton notes “2 vials of 6 mL.” This refers to the vial size (not the actual content within the vial).
- This presentation contains 2 vials of 2.5 mL (one of casirivimab and one of imdevimab).
- Please note that co-packs carry the Roche logo and do not show the REGEN-COV™ brand name.



Labeling

In addition to the packaging configurations noted above, some REGEN-COV™ carton and vial labels may have statements such as “Solution for Intravenous Administration” or “For Intravenous Infusion after Dilution”. **Any of these REGEN-COV™ vials may be used to prepare and administer intravenous infusions as well as subcutaneous injections**, even though there is no language on the label that states the subcutaneous route is appropriate.

Storage and Stability of Prepared Doses

Infusion: If immediate administration is not possible, store the diluted casirivimab and imdevimab infusion solution in the refrigerator between 2°C to 8°C (36°F to 46°F) for no more than 36 hours or at room temperature up to 25°C (77°F) for no more than 4 hours. If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 30 minutes prior to administration.

Subcutaneous Syringes: This product is preservative-free and therefore the prepared syringes should be administered immediately. If immediate administration is not possible, store the prepared casirivimab and imdevimab syringes in the refrigerator between 2°C to 8°C (36°F to 46°F) for no more than 4 hours or at room temperature up to 25°C (77°F) for no more than 4 total hours. If refrigerated, allow the syringes to equilibrate to room temperature for approximately 20 minutes prior to administration.

Medical Information Inquiries and Additional References

- Medical information inquiries should be referred to Regeneron Medical Information at 1-844-734-6643.
- For the most up-to-date information, always refer to the product Fact Sheet, Emergency Use Authorization guidance, and other materials as posted online at www.regencov.com.
- See dosing and administration for more information (<https://www.regencov.com/hcp/dosing/packaging>).