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 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](http://www.regencov.com).
- See dosing and administration for more information ([https://www.regencov.com/hcp/dosing/packaging](https://www.regencov.com/hcp/dosing/packaging)).