

CASIRIVIMAB AND IMDEVIMAB

Scan the QR code or go to www.REGENCOV2.com for the FDA-authorized Fact Sheet for detailed preparation and administration instructions for casirivimab and imdevimab.



Casirivimab and imdevimab carton and vial labels may instead be labeled REGN10933 and REGN10987 respectively.

Casirivimab and imdevimab may each be supplied as 1,332 mg/11.1 mL (120 mg/mL) single-dose vials OR 300 mg/2.5 mL (120 mg/mL) single-dose vials.

One 11.1 mL vial of one antibody and four 2.5 mL vials of the other antibody can be used to create one treatment course.

**CASIRIVIMAB AND IMDEVIMAB MUST BE ADMINISTERED TOGETHER
AFTER DILUTION BY INTRAVENOUS (IV) INFUSION ONLY.**

You may receive cartons and vials of casirivimab and imdevimab that are labeled “for intravenous infusion or subcutaneous injection”. However, casirivimab and imdevimab MUST be administered by INTRAVENOUS (IV) INFUSION ONLY under this emergency use authorization.

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.

LIMITATIONS OF AUTHORIZED USE

- Casirivimab and imdevimab are not authorized for use in patients:
 - who are hospitalized due to COVID-19, OR
 - who require oxygen therapy due to COVID-19, OR
 - who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.
- Benefit of treatment with casirivimab and imdevimab has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as casirivimab and imdevimab, may be associated with worse clinical outcomes when administered to hospitalized patients requiring high flow oxygen or mechanical ventilation with COVID-19.

Health care providers must submit a report on all medication errors and **ALL SERIOUS ADVERSE EVENTS** potentially related to casirivimab and imdevimab. See Sections 8 and 9 of the Full EUA Prescribing Information for reporting instructions.