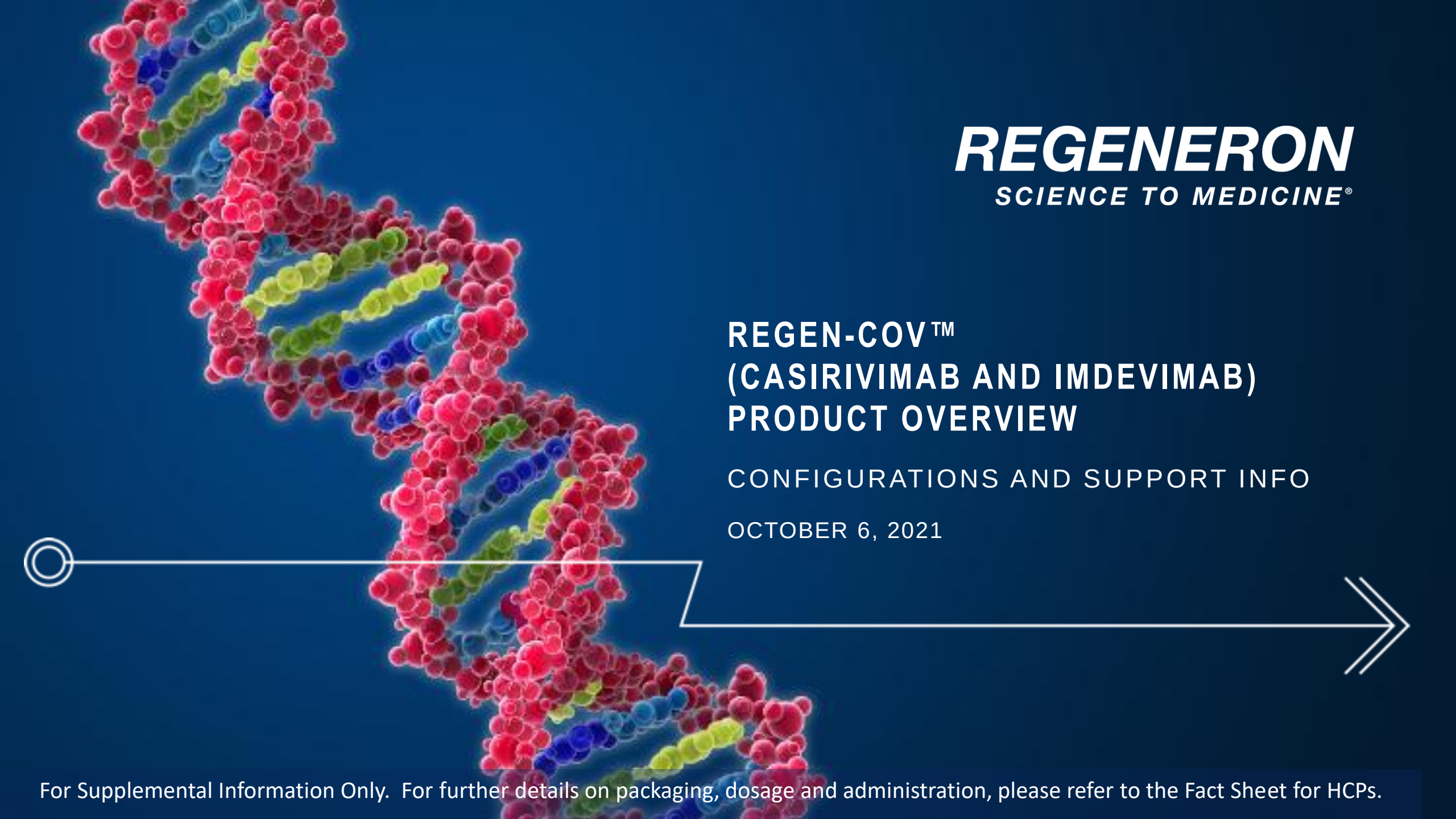

REGENERON
SCIENCE TO MEDICINE®

REGEN-COV™ (CASIRIVIMAB AND IMDEVIMAB) PRODUCT OVERVIEW

CONFIGURATIONS AND SUPPORT INFO

OCTOBER 6, 2021

For Supplemental Information Only. For further details on packaging, dosage and administration, please refer to the Fact Sheet for HCPs.

DISCLAIMER

- This presentation is for supplemental information only and has been prepared at the request of ASPR
- It is not meant to address any clinical or product administration questions
- Medical information inquiries should be referred to Regeneron Medical Information at 1-844-734-6643
- The images contained herein are for reference only
- For the most up-to-date information always refer to the Fact Sheet, Emergency Use Authorization guidance and other materials as posted online at www.regencov.com
- Some content within this presentation refers to information within the AmerisourceBergen systems and is provided in support of streamlining allocation processes and ordering for sites

REGEN-COV™ PRODUCT DESCRIPTIONS

You May Have Previously Received Co-formulated Product;
Dose Packs Have Important Differences

REGEN-COV = casirivimab + imdevimab

- REGEN-COV™ CO-FORMULATED vial: slide 4
- REGEN-COV™ Dose Packs (2-Vial): slides 5-7
- Casirivimab and Imdevimab Co-Pack (2 vials per carton): slide 8

1,200mg dose = 10mL (5mL of each Antibody)

For Supplemental Information Only. For further details on packaging, dosage and administration, please refer to the Fact Sheet for HCPs.

REGEN-COV™ MASTER NDC/PRODUCT TABLE

Description ALL product is 120mg/mL strength	NDC of package	Number of DOSES contained in package at 1,200mg dose	Number of individual vials in package
REGEN-COV™ CO-FORMULATED vial 600mg/600mg 10mL	61755-039-01	1	1
REGEN-COV™ Dose Packs (2-Vial) 1332mg/11.1mL	61755-035-02	2	2
Casirivimab and Imdevimab Co-Pack (2 vials per carton) 300mg/2.5mL in 6mL vials *Includes Quick Reference Guide to explain Pandemic label Roche product	61755-045-02	½ dose (2 co-packs required for 1 dose)	2

REGEN-COV Packaging: https://www.regencov.com/hcp/dosing/packaging
REGEN-COV EUA Fact Sheet: https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf

For Supplemental Information Only. For further details on packaging, dosage and administration, please refer to the Fact Sheet for HCPs.

REGEN-COV™ CO-FORMULATED VIAL

ONE (1) CO-FORMULATED VIAL = 1 DOSE @ 1,200MG

CO-FORMULATED REGEN-COV

600 mg of casirivimab and 600 mg of imdevimab per 10 mL (60 mg/60 mg per mL) in a single vial

One vial (10mL) = one dose of 1,200mg REGEN-COV

1 VIAL PER CARTON

NDC 61755-039-01

REGEN-COV Packaging: https://www.regencov.com/hcp/dosing/packaging
REGEN-COV EUA Fact Sheet: https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf

The FDA has authorized co-formulated vials to be administered as intravenous or subcutaneous

For Supplemental Information Only. For further details on packaging, dosage and administration, please refer to the Fact Sheet for HCPs.

REGEN-COV™ DOSE PACKS (2-VIAL)

ONE (1) DOSE PACK = 2 DOSES @ 1,200MG

REGEN-COV DOSE PACKS

Each REGEN-COV 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, respectively.

Casirivimab or imdevimab as individual antibody solutions in separate 11.1 mL vials may be used to prepare more than one dose simultaneously as appropriate, either in intravenous bags or in syringes for subcutaneous injection. Discard any product remaining in the vials.

Keep any unopened vials of casirivimab and imdevimab in their original carton in the refrigerator.

Though the dose pack is labeled to contain one treatment dose, this is incorrect. Each dose pack contains 1,200 mg of casirivimab and 1,200 mg of imdevimab that can be used to prepare multiple doses for treatment or post-exposure prophylaxis.

2 CARTON DOSE PACK

1 VIAL OF CASIRIVIMAB
11.1 mL
NDC 61755-024-01

AND

1 VIAL OF IMDEVIMAB
11.1 mL
NDC 61755-025-01

REGEN-COV Packaging: https://www.regencov.com/hcp/dosing/packaging
REGEN-COV EUA Fact Sheet: https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf

For Supplemental Information Only. For further details on packaging, dosage and administration, please refer to the Fact Sheet for HCPs.

REGEN-COV DOSE PACKS (2-VIAL) - CONTINUED

A Dose Pack Label
B Carton Images

✓ This label is on the dose pack bag

A

NDC 61755-**035**-02

FPO
3 61755 03502 1

REGEN-COV™

[casirivimab (REGN10933) with imdevimab (REGN10987)]

This dose pack provides one complete dose, and contains:
- 1 vial of casirivimab 1332 mg/11.1 mL (120 mg/mL)
- 1 vial of imdevimab 1332 mg/11.1 mL (120 mg/mL)

Must dilute and administer together via intravenous infusion.

Refer to FDA-authorized Fact Sheet for detailed preparation and administration instructions.

For Use under Emergency Authorization (EUA).

Do not open this dose pack until time of dose preparation.
Store dose pack refrigerated between 2°C - 8°C (36 °F to 46 °F).
Do Not Freeze.

Dose Pack Lot #:_____

FPO
000000

REGENERON

Bar code for Manufacturer internal use only.

TEL: +1 844-734-6643

Carton Images

B

A

Original EUA = 2,400mg dose

The FDA has since authorized a lower REGEN-COV dose at 1,200mg.

Thus, each dose pack equates to TWO (2) doses

The FDA has authorized dose packs to be administered as intravenous or subcutaneous

REGEN-COV Packaging: https://www.regencov.com/hcp/dosing/packaging
REGEN-COV EUA Fact Sheet: https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf

INSIDE EACH DOSE PACK: DIRECTIONS TO ACCESS FACT SHEETS

QR Code Reference Sheet Approval Page – English

REGEN-COV™ (casirivimab with imdevimab) DOSE PACK

Information for REGEN-COV under Emergency Use Authorization (EUA) for Treatment of Patients with COVID-19

Casirivimab and imdevimab are monoclonal antibodies authorized for emergency use by the U.S. Food and Drug Administration (FDA) 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. Refer to the FDA Fact Sheet for Health Care Providers for the Limitations of Authorized Use.

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

It is important to note:

- **Each REGEN-COV dose pack contains sufficient number of vials of Casirivimab (REGN10933) and Imdevimab (REGN10987) to prepare one treatment dose.**
  - **Casirivimab and Imdevimab carton and vial labels may instead be labeled REGN10933 and REGN10987 respectively.**
- **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.**
- The barcode on the carton and container may not accurately register. Confirm that the barcode provides correct information when scanned and if not, consider to manually input the product into electronic systems.
- Casirivimab injection and Imdevimab injection 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.

Health care providers must submit a report on all medication errors and ALL SERIOUS ADVERSE EVENTS potentially related to REGEN-COV (casirivimab with imdevimab). See the FDA Fact Sheet for Health Care Providers (Sections 8 and 9 of the Full EUA Prescribing Information) for reporting instructions.

QR Code Reference Sheet Approval Page – Spanish

PAQUETE DE DOSIS DE REGEN-COV™ (casirivimab con imdevimab)

Información para REGEN-COV en virtud de la Autorización de uso de emergencia (Emergency Use Authorization, EUA) para el tratamiento de pacientes con COVID-19

Casirivimab e imdevimab son anticuerpos monoclonales autorizados para uso de emergencia por la Administración de Alimentos y Medicamentos de los Estados Unidos (U.S. Food and Drug Administration, FDA) para la administración conjunta para el tratamiento de la enfermedad por coronavirus 2019 (COVID-19) leve a moderada en adultos y pacientes pediátricos (de 12 años de edad en adelante y que pesen, al menos, 40 kg) con resultados positivos en pruebas virales de detección directa de SARS-CoV-2 y con alto riesgo de que evolucionen a una forma grave de COVID-19 y/o sean hospitalizados únicamente mientras dure la declaración. Para conocer las Limitaciones del uso autorizado, consulta la Ficha técnica de la FDA para Proveedores de atención médica.

Para obtener la ficha técnica autorizada por la FDA con instrucciones detalladas sobre la preparación y la administración de casirivimab e imdevimab, escanea el código QR o visita www.REGENCOV.com.

Es importante destacar lo siguiente:

- **Cada paquete de dosis de REGEN-COV contiene la cantidad suficiente de viales de casirivimab (REGN10933) y de imdevimab (REGN10987) para preparar una dosis de tratamiento.**
  - **Es posible que las cajas y los viales de casirivimab e imdevimab estén etiquetados como REGN10933 y REGN10987, respectivamente.**
- **Casirivimab e imdevimab DEBEN ADMINISTRARSE DE MANERA CONJUNTA después de su dilución mediante infusión intravenosa (IV) únicamente.**
- **Puedes recibir cajas y viales de casirivimab e imdevimab en cuya etiqueta se indique "para infusión intravenosa o inyección subcutánea". Sin embargo, casirivimab e imdevimab DEBEN administrarse mediante INFUSIÓN INTRAVENOSA (IV) ÚNICAMENTE conforme a esta autorización de uso de emergencia.**
- El código de barras en la caja y en el contenedor puede no estar registrado con exactitud. Confirma que el código de barras brinda la información correcta cuando lo escaneas y, de no ser así, considera ingresar manualmente el producto en los sistemas electrónicos.
- La inyección de casirivimab y la inyección de imdevimab pueden suministrarse por separado en viales monodosis de 1,332 mg/11.1 ml (120 mg/ml) O en viales monodosis de 300 mg/2.5 ml (120 mg/ml).

Los proveedores de atención médica deben enviar un informe sobre todos los errores de medicación y TODOS LOS EVENTOS ADVERSOS GRAVES potencialmente relacionados con REGEN-COV (casirivimab con imdevimab). Consulta la Ficha técnica de la FDA para Proveedores de atención médica (Secciones 8 y 9 de la Información completa de prescripción de la EUA) para obtener instrucciones sobre cómo realizar dicho informe.

For Supplemental Information Only. For further details on packaging, dosage and administration, please refer to the Fact Sheet for HCPs.

CASIRIVIMAB AND IMDEVIMAB CO-PACK (2 VIALS PER CARTON)

TWO (2) CARTONS = 1 DOSE @ 1,200MG

REGEN-COV CO-PACK

Casirivimab or imdevimab as individual antibody solutions in separate 11.1 mL vials may be used to prepare more than one dose simultaneously as appropriate, either in intravenous bags or in syringes for subcutaneous injection. Discard any product remaining in the vials.

Keep any unopened vials of casirivimab and imdevimab in their original carton in the refrigerator.

Although the carton is labeled "2 vials of 6 mL," this is referring to the vial size and not the content of the vial.
This presentation contains 2 vials of 2.5 mL (one of casirivimab and one of imdevimab)

Note that co-packs carry the Roche logo and do not show the REGEN-COV brand name.

2.5 ML VIALS CO-PACK

1 VIAL OF CASIRIVIMAB
2.5 mL
NDC 61755-026-00

AND

1 VIAL OF IMDEVIMAB
2.5 mL
NDC 61755-027-00

The FDA has authorized co-packs to be administered as intravenous or subcutaneous

REGEN-COV Packaging: https://www.regencov.com/hcp/dosing/packaging
REGEN-COV EUA Fact Sheet: https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf

For Supplemental Information Only. For further details on packaging, dosage and administration, please refer to the Fact Sheet for HCPs.

WITH EACH CO-PACK: DIRECTIONS TO ACCESS FACT SHEETS

QR Code Reference Sheet Approval Page

Casirivimab and Imdevimab (also known as REGEN-COV™) Co-Packaged Product Quick Reference Guide

Information for Temporary Alternative Packaging of REGEN-COV under Emergency Use Authorization (EUA)

Scan the QR code or go to www.REGENCOV.com for the FDA-authorized Fact Sheets (one for the Healthcare Provider and one for the Patient/Caregiver) for current product information for casirivimab and imdevimab.

It is important to note:

- **Each co-packaged carton contains individual antibody solutions in separate vials as follows:**
  - **One (1)** vial containing casirivimab; 300 mg/2.5 mL (120 mg/mL) or 1,332 mg/11.1 mL (120 mg/mL)
  - **One (1)** vial containing imdevimab; 300 mg/2.5 mL (120 mg/mL) or 1,332 mg/11.1 mL (120 mg/mL)
  - One (1) package leaflet which is not approved for use in the US. **This leaflet should be discarded. Please refer to the authorized EUA Fact Sheets only (scan the QR code above).**
- **The carton is labeled as "casirivimab and imdevimab 120 mg/mL concentrate for solution for infusion".** Do not confuse this co-packaged carton with REGEN-COV (casirivimab and imdevimab) co-formulated solution.
- **The vials in the co-packaged carton may be used to prepare and administer intravenous infusions as well as subcutaneous injections** despite having the statements such as "Concentrate for solution for infusion" or "For intravenous infusion after dilution".
- Carton and vial labels do not include an NDC. Use the NDC listed below based on the package.

Co-Packaged Carton Contents	Co-Packaged Components	Concentration	Co-Packaged Carton NDC Number
2 Vials	1 vial of casirivimab (NDC 61755-024-00)	1,332 mg/11.1 mL (120 mg/mL)	61755-042-02
	1 vial of imdevimab (NDC 61755-025-00)	1,332 mg/11.1 mL (120 mg/mL)	
2 Vials	1 vial of casirivimab (NDC 61755-026-00)	300 mg/2.5 mL (120 mg/mL)	61755-045-02
	1 vial of imdevimab (NDC 61755-027-00)	300 mg/2.5 mL (120 mg/mL)	

- **The barcode on the co-packaged carton label may not register with U.S. scanning systems.** Confirm that the barcode provides correct information when scanned and if not, consider manually inputting the product specific information into electronic systems. There is no barcode on the co-packaged vial.
- Roche manufactures the co-packaged product on behalf of Regeneron and is listed on the package.
- Refer to the "Dear Healthcare Provider Letter" for additional information on the co-packaged product.

Health care providers must submit a report on **ALL MEDICATION ERRORS and ALL SERIOUS ADVERSE EVENTS** potentially related to REGEN-COV (casirivimab and imdevimab). See the FDA Fact Sheet for Health Care Providers (Sections 8 and 9 of the Full EUA Prescribing Information) for reporting instructions.

If you have questions, please contact Regeneron at 1-844-734-6643.

REGENERON

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