Casirivimab (a.k.a. REGN10933) Injection (120 mg/ml)

MUST ADMINISTER WITH IMDEVIMAB

Manufacturer: Regeneron Pharmaceuticals, Inc.

Distributor: AmerisourceBergen (a.k.a. ABC); c19therapies@amerisourcebergen.com

Product: Component of 2-drug monoclonal antibody cocktail for outpatient infusion

Emergency Use Authorization (EUA): 11/21/20

Units: Supplied in 2 volumes

- 1332 mg/11.1 ml single-dose vial in carton (10 ml from 1 vial needed for patient course)
- 300 mg/2.5 ml single-dose vials in cartons (10 ml; 2.5 ml from each of 4 vials needed for patient course)

Note: Some cartons and vials of casirivimab may be instead labeled REGN10933





Example: 1332 mg/11.1 ml carton

Example: 300 mg/2.5 ml carton



Example: Manufacturer's label for case of Example: 2.5 ml & 11.1 ml vials 11.1 ml vials (REGN10933)

Storage: Keep in carton until use. Unopened vials must be stored at refrigerated temperature (2°C–8°C / 36°F–46°F) until use. Do not freeze, shake, or expose to direct light.

Earliest Expiration Date of Units Shipped: 06/2022

Single Vial w/ Carton Dimensions: 1.7"(d) x 1.8"(w) x 2.8"(h)

Single Vial w/ Carton Weight: 1.5 oz. for 1332 mg/11.1 ml vial; 0.9 oz. for 300 mg/2.5 ml vial

Case: A full case contains 24 vials in cartons **Case Dimensions:** 9.6"(d) x 7.4"(w) x 4.6"(h)

Case Weight: 2.7 lb. for 1332mg/11.1 ml vials; 1.8 lb. for 300 mg/2.5 ml vials

Administration: (For detailed guidelines, click here)

- 1. Remove 20 ml from 250-ml normal saline IV bag
- 2. Inject 10 ml (1200 mg) casirivimab
- 3. Inject 10 ml (1200 mg) imdevimab
- 4. Infuse final volume (250 ml) containing cocktail of 2 monoclonal antibodies over at least 60 min

Note: If immediate patient infusion is not possible, store the diluted cocktail solution at refrigerated temperature ($2^{\circ}C-8^{\circ}C/36^{\circ}F-46^{\circ}F$) for no more than 36 hours and at room temperature for no more than 4 hours, including infusion time.

Resources/Links:

- Regeneron webpage, including:
 - o FDA Letter of Authorization
 - Fact Sheet for Healthcare Providers
 - Fact Sheet for Patients and Caregivers (English)
 - Fact Sheet for Patients and Caregivers (Spanish)
- FDA Frequently Asked Questions on the EUA for Casirivimab + Imdevimab
- FAQ: Allocation, Distribution, and Administration of Casirivimab + Imdevimab

Imdevimab (a.k.a. REGN10987) Injection (120 mg/ml)

MUST ADMINISTER WITH CASIRIVIMAB

Manufacturer: Regeneron Pharmaceuticals, Inc.

Distributor: AmerisourceBergen (a.k.a. ABC); c19therapies@amerisourcebergen.com

Product: Component of 2-drug monoclonal antibody cocktail for outpatient infusion

Emergency Use Authorization (EUA): 11/21/20

Units: Supplied in 2 volumes

- 1332 mg/11.1 ml single-dose vial in carton (10 ml from 1 vial needed for patient course)
- 300 mg/2.5 ml single-dose vials in cartons (10 ml; 2.5 ml each from 4 vials needed for patient course)

Note: Some cartons and vials of imdevimab may be instead labeled REGN10987





Example: 1332 mg/11.1 ml carton

Example: 300 mg/2.5 ml carton



Example: Manufacturer's label for case of 11.1 ml vials (REGN10987)

Example: 2.5 ml & 11.1 ml vials

Storage: Keep in carton until use. Unopened vials must be stored at refrigerated temperature (2°C–8°C / 36°F–46°F) until use. Do not freeze, shake, or expose to direct light.

Earliest Expiration Date of Units Shipped: 06/2022

Single Vial w/ Carton Dimensions: 1.7"(d) x 1.8"(w) x 2.8"(h)

Single Vial w/ Carton Weight: 1.5 oz. for 1332 mg/11.1 ml vial; 0.9 oz. for 300 mg/2.5 ml vial

Case: A full case contains 24 vials in cartons **Case Dimensions:** 9.6"(d) x 7.4"(w) x 4.6"(h)

Case Weight: 2.7 lb. for 1332mg/11.1 ml vials; 1.8 lb. for 300 mg/2.5 ml vials

Administration: (For detailed guidelines, click here)

- 5. Remove 20 ml from 250-ml normal saline IV bag
- 6. Inject 10 ml (1200 mg) casirivimab
- 7. Inject 10 ml (1200 mg) imdevimab
- 8. Infuse final volume (250 ml) containing cocktail of 2 monoclonal antibodies over at least 60 min *Note: If immediate patient infusion is not possible, store the diluted cocktail solution at refrigerated*

temperature $(2^{\circ}C-8^{\circ}C/36^{\circ}F-46^{\circ}F)$ for no more than 36 hours and at room temperature for no more than 4 hours, including infusion time.

Resources/Links:

- Regeneron webpage, including:
 - FDA Letter of Authorization
 - Fact Sheet for Healthcare Providers
 - Fact Sheet for Patients and Caregivers (English)
 - Fact Sheet for Patients and Caregivers (Spanish)
- FDA Frequently Asked Questions on the EUA for Casirivimab + Imdevimab
- FAQ: Allocation, Distribution, and Administration of Casirivimab + Imdevimab