

139mm

# Comder<sup>100mg</sup> Injection

## Remdesivir Lyophilized Powder For IV Infusion

### COMPOSITION:

Each Lyophilized vial Contains:  
Remdesivir ..... 100mg  
(As per innovator's specifications)

### DESCRIPTION:

Remdesivir is a broad-spectrum antiviral medication. Remdesivir is a nucleoside ribonucleic acid (RNA) polymerase inhibitor. The chemical name for Remdesivir is 2-ethylbutyl N-((S)-[2-C-(4-aminopyrrolo[2,1-f][1,2,4]triazin-7-yl)-2,5-anhydro-d-altronoitriol-6-Oyl]phenoxyphosphoryl)-L-alaninate. It has a molecular formula of C<sub>21</sub>H<sub>28</sub>N<sub>6</sub>O<sub>8</sub>P and a molecular weight of 602.6 g/mol.  
Remdesivir for injection, 100 mg, is a sterile, preservative-free lyophilized powder that is to be reconstituted prior to administration. The appearance of the lyophilized powder is white to off-white to yellow.

### AUTHORIZED USE:

Remdesivir is an investigational antiviral drug. The EUA (Emergency Use Authorization) by FDA allows Remdesivir to treat adults and children hospitalized with severe COVID-19.

Severe COVID-19 is defined as patients with oxygen saturation (SpO<sub>2</sub>) ≤ 94% on room air or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane oxygenation (ECMO), a heart-lung bypass machine.

### MECHANISM OF ACTION:

Remdesivir, a pro-drug, is metabolized within cells into an alanine metabolite, further processed into the monophosphate derivative and ultimately into the active nucleoside triphosphate derivative. The resulting triphosphate derivative acts as an analog of adenosine triphosphate (ATP) and inhibits RNA polymerase, which results in delayed chain termination during replication of the viral RNA.

### PHARMACOKINETICS:

The pharmacokinetics (PK) of Remdesivir has been evaluated in adults. Following single-dose, 2-hour IV administration of Remdesivir solution formulation at doses ranging from 3 to 225 mg, Remdesivir exhibited a linear PK profile. Pharmacokinetic differences based on sex, race, and age have not been evaluated. The pharmacokinetics of Remdesivir in pediatric patients has also not been evaluated. Because the excipient SBECD is renally cleared and accumulates in patients with decreased renal function, administration of Remdesivir (formulated with SBECD) is not recommended in adult and pediatric patients with renal impairment.

### SIDE EFFECTS:

An infusion reaction may occur with Remdesivir with symptoms such as:

- Low blood pressure,
- Dizziness, and slow/fast heartbeat,
- Nausea,
- Vomiting,
- Sweating, and shivering

A slower rate of infusion may help to lessen the risk of this reaction. In the case of a serious allergic reaction, symptoms may include:

- Rash/itching/swelling (especially of the face/tongue/throat)
- Severe dizziness
- Trouble breathing

### DRUG INTERACTIONS:

Drug-drug interactions of Remdesivir with any other concomitant medications have not been evaluated in humans. Due to antagonism observed in vitro, concomitant use of Remdesivir with chloroquine phosphate or hydroxychloroquine sulfate is not recommended.

### CONTRAINDICATIONS:

Remdesivir is contraindicated in patients with known hypersensitivity to any ingredient of Remdesivir for injection. Because the excipient SBECD is renally cleared and accumulates in patients with decreased renal function, administration of Remdesivir (formulated with SBECD) is not recommended in adult and pediatric patients with renal impairment.

### PRECAUTION & WARNINGS:

Prior to and during treatment with Remdesivir, following points should be noted:

- Adult and pediatric patients (greater than 28 days old) must have serum creatinine determined before dosing of Remdesivir and daily while receiving Remdesivir.
- Hepatic laboratory testing should be performed in all patients prior to starting Remdesivir and daily while receiving Remdesivir.
- Remdesivir should be administered via IV infusion only.
- Do not administer as an intramuscular (IM) injection.

### DOSAGE AND ADMINISTRATION:

#### Recommended Dosage in Adult Patients:

- The recommended dosage in adults is a single loading dose of Remdesivir 200 mg on Day 1 followed by once-daily maintenance doses of Remdesivir 100 mg from Day 2 via IV infusion.
- For patients requiring invasive mechanical ventilation and/or ECMO, total treatment duration is 10 days.
- For patients not requiring invasive mechanical ventilation and/or ECMO, total treatment duration is 5 days. If a patient does not demonstrate clinical improvement, treatment may be extended for up to 5 additional days (i.e., up to a total of 10 days).
- Administered Remdesivir vial IV infusion in a total volume of up to 250 mL 0.9% sodium chloride over 30 to 120 minutes

#### Recommended Dosage in Pediatric Patients:

- For pediatric patients weighing 3.5 kg to less than 40 kg, use Remdesivir for injection, 100 mg, lyophilized powder only.
- For pediatric patients weighing 3.5 kg to less than 40 kg, the dose should be calculated using the mg/kg dose according to the patient's weight.
- For pediatric patients requiring invasive mechanical ventilation and/or ECMO, total treatment duration is 10 days.
- For pediatric patients not requiring invasive mechanical ventilation and/or ECMO, total treatment duration is 5 days. If a patient does not demonstrate clinical improvement, treatment may be extended for up to 5 additional days (i.e., up to a total of 10 days).
- Recommended dosage of Remdesivir Lyophilized Powder for Injection in pediatric patients with body weight 3.5 kg to less than 40 kg is 5 mg/kg on Day 1 followed by once-daily maintenance doses of Remdesivir 2.5 mg/kg from Day 2 via IV infusion.
- Recommended dosage of Remdesivir Lyophilized Powder for Injection in pediatric patients with body weight higher than 40 kg 200 mg on Day 1 followed by once-daily maintenance doses of Remdesivir 100 mg from Day 2 via IV infusion.

203mm

### HOW SUPPLIED:

Remdesivir for injection, 100 mg, is supplied as a single-dose vial containing a sterile, preservative-free white to off-white to yellow lyophilized powder that is to be reconstituted with 19 mL of Sterile Water for Injection and further diluted into 0.9% sodium chloride infusion bag prior to administration by intravenous infusion.

### RECONSTITUTION INSTRUCTIONS:

- Aseptically reconstitute Remdesivir lyophilized powder by addition of 19 mL of Sterile Water for Injection
- Immediately shake the vial for 30 seconds to dissolve the powder. Repeat this procedure as necessary until the contents of the vial are completely dissolved.
- Care should be taken during admixture to prevent inadvertent microbial contamination
- Discard the vial if a vacuum does not pull the Sterile Water for Injection into the vial.
- Following reconstitution, each vial contains 100 mg/20 mL (5 mg/mL) of Remdesivir solution.
- The reconstituted Remdesivir lyophilized powder for injection, containing 100 mg/20 mL Remdesivir solution, should be further diluted in 100 mL or 250 mL 0.9% sodium chloride infusion bags.
- Withdraw & discard volume from 0.9% sodium chloride infusion bag given in below tables.
- Withdraw the required volume of reconstituted Remdesivir for injection from the Remdesivir vial and transfer the required volume to the selected infusion bag.
- Gently invert the bag 20 times to mix the solution in the bag. Do not shake.
- The prepared diluted solution is stable for 4 hours at room temperature (20°C to 25°C) or 24 hours in the refrigerator at 2°C to 8°C.

**TABLE 1: Recommended Dilution Instructions Using Reconstituted Remdesivir for Injection Lyophilized Powder in Adults and Pediatric Patients Weighing 40 kg and Higher**

| Infusion bag volume | Infusion time | Rate of infusion |
|---------------------|---------------|------------------|
| 100 mL              | 30 min        | 3.33 mL/min      |
|                     | 60 min        | 1.67 mL/min      |
|                     | 120 min       | 0.83 mL/min      |
| 50 mL               | 30 min        | 1.67 mL/min      |
|                     | 60 min        | 0.83 mL/min      |
|                     | 120 min       | 0.42 mL/min      |
| 25 mL               | 30 min        | 0.83 mL/min      |
|                     | 60 min        | 0.42 mL/min      |
|                     | 120 min       | 0.21 mL/min      |

**TABLE 2: Recommended Rate of Infusion — Diluted Remdesivir for Injection Lyophilized Powder in Adults and Pediatric Patients Weighing 40 kg and Higher**

| Remdesivir dose | 0.9% sodium chloride infusion bag volume to be used | Volume to be withdrawn & discarded from 0.9% NaCl infusion bag | Required volume of reconstituted Remdesivir for injection |
|-----------------|-----------------------------------------------------|----------------------------------------------------------------|-----------------------------------------------------------|
| 200 mg (2 vial) | 250 mL                                              | 40 mL                                                          | 40 mL (2 X 20 mL)                                         |
|                 | 100 mL                                              | 40 mL                                                          | 40 mL (2 X 20 mL)                                         |
| 100 mg (1 vial) | 250 mL                                              | 20 mL                                                          | 20 mL                                                     |
|                 | 100 mL                                              | 20 mL                                                          | 20 mL                                                     |

**TABLE 3: Recommended Rate of Infusion—Diluted Remdesivir for Injection Lyophilized Powder for Pediatric Patients Weighing 3.5 kg to Less Than 40 kg**

| Infusion bag volume | Infusion time | Rate of infusion |
|---------------------|---------------|------------------|
| 250 mL              | 30 min        | 8.33 mL/min      |
|                     | 60 min        | 4.17 mL/min      |
|                     | 120 min       | 2.08 mL/min      |
| 100 mL              | 30 min        | 3.33 mL/min      |
|                     | 60 min        | 1.67 mL/min      |
|                     | 120 min       | 0.83 mL/min      |

Note: Rate of infusion may be adjusted based on total volume to be infused.

### STORAGE AND HANDLING:

Store Remdesivir for injection, 100 mg, vials below 30°C until required for use. Don't use after expiration date. After reconstitution, vials can be stored up to 4 hours at room temperature (20°C to 25°C) prior to administration or 24 hours at refrigerated temperature (2°C to 8°C). Dilute within the same day as administration.

### INSTRUCTIONS:

Keep out of reach of children. Protect from sunlight & moisture. To be sold on the prescription of a registered medical practitioner only.

### PRESENTATION:

Remdesivir for injection, 100mg, is supplied in a single-dose clear glass vial.

Marketed by:



Manufactured by:

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