

LABELLING

MINIMUM PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

- 1. Name of the medicinal product**
[CV001 trade name]* Remdesivir 100 mg powder for solution for injection
- 2. List of excipients**
See patient information leaflet.
- 3. Pharmaceutical form and contents**
Powder for solution for injection
6 x 1 vials
- 4. Method and route of administration**
For intravenous use.
Read the patient information leaflet before use.
- 5. Special warning that the medicinal product must be stored out of the reach and sight of children**
Keep out of the reach of children.
- 6. Other special warning(s), if necessary**
- 7. Expiry date**
EXP {MM/YYYY}
- 8. Special storage conditions**
Store below 30°C until time of use. Do not freeze.

After reconstitution, vials can be stored up to 4 hours at 20°C to 25°C. Excursions allowed between 15°C and 30°C or 24 hours in the refrigerator at 2°C to 8°C.
- 9. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**
- 10. Name and address of the supplier**
Hetero Labs Limited
7-2-A2, Hetero Corporate
Industrial Estates
Sanath Nagar, Hyderabad-500 018
Telangana, India
- 11. WHO Reference Number (Prequalification Programme)**
CV001
- 12. Manufacturer's batch number**
<Batch> <Lot> {number}
- 13. (Advice on) General classification for supply**
Medicinal product subject to medical prescription.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

14. Instructions on use

Read the patient information leaflet before use.

**MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING
Vial**

- 1. Name of the medicinal product**
[CV001 trade name] Remdesivir 100 mg powder for solution for injection
- 2. Method and route of administration**
For intravenous use.
- 3. Expiry date**
EXP {MM/YYYY}
- 4. Name and address of the supplier**
Hetero Labs Ltd
- 5. Manufacturer's batch number**
<Batch> <Lot> {number}
- 6. (Advice on) General classification for supply**
Medicinal product subject to medical prescription.