

Remdinil™

Remdesivir INN

100 mg

Composition:

Remdinil™ 100 mg Conc. Solution: Each vial contains Remdesivir 100 mg/20 ml concentrate for solution for IV infusion.

Pharmacology:

Remdesivir is a prodrug of a modified adenine nucleoside analogue. Remdesivir undergoes efficient metabolic conversion in cells and tissues to active nucleoside triphosphate metabolite that inhibits viral RNA polymerases, but not host RNA or DNA polymerases. Remdesivir exhibits a potential for clinical efficacy against Ebola virus and other filovirus infections

Indication and usage:

For the treatment of suspected or laboratory confirmed Corona Virus Disease 2019 (COVID-19) in adult and children hospitalized with severe disease. Severe disease is defined as patients with an oxygen saturation (SpO₂) ≤ 94% on room air or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane oxygenation (ECMO). Specifically, Remdesivir is only authorized for hospitalized adults and pediatric patients for whom use of an intravenous agent is clinically appropriate.

Dosage and Administration:

The recommended dosing and duration of Remdesivir in adults is 200 mg on the first day followed by 9 days of 100 mg once daily to be administered via IV infusion in a total volume of up to 250 mL of 0.9% saline over 30 minutes. The infusion time may be extended up to 120 minutes.

The recommended RDV dosing duration is a total of 10 days

Method of Administration:

Concentrate for solution for infusion 100 mg:

- Dilute concentrated solution in intravenous fluids up to 250 mL prior to intravenous administration.
- Diluents that may be used: 0.9 % (9 mg/ml) sodium chloride in water for injection (saline)
- The diluted solutions should be used immediately.

Side effects:

Multiple-dose IV administration of Remdesivir 150 mg once-daily for 7 or 14 days was generally well tolerated.

Contraindications:

- Hypersensitivity to the active substance(s) or to any of the excipients
- Evidence of multiorgan failure
- The use of more than one pressor for septic shock (the use of 1 pressor at low/medium doses for inotropic support due to the use of sedation and paralytics while on the ventilator is allowed)
- ALT > 5 x upper limit of normal (ULN) by local laboratory measure
- Renal failure (eGFR < 30 mL/min) or dialysis or continuous veno-venous hemofiltration
- Participation in any other clinical trial of an experimental agent treatment for other viruses

Precautions:

In clinical studies, transient elevations in ALT and AST have been observed with single doses of Remdesivir up to 225 mg and multiple once-daily doses of Remdesivir 150 mg for up to 14 days, with mild, reversible PT prolongation in some subjects but without any clinically relevant change in INR or other evidence of hepatic effects. The mechanism of these elevations is currently unknown.

In nonclinical animal studies, toxicity findings were consistent with dose-dependent and reversible kidney injury and dysfunction. In clinical studies, no evidence of nephrotoxicity has been observed with single doses of Remdesivir up to 225 mg or multiple once-daily doses of Remdesivir 150 mg for up to 14 days.

Interactions:

No clinical drug-drug interaction studies have been conducted with Remdesivir.

Remdesivir should not be used with other drugs that have significant hepatotoxicity.

Pregnancy and lactation:

Pregnancy and contraception requirements There are no data from the use of Remdesivir in pregnant women. The use of Remdesivir in pregnant woman is not recommended.

Breast-feeding: It is unknown whether Remdesivir/metabolites are excreted in human milk.

Fertility: No human data on the effect of Remdesivir on fertility are available.

Overdose:

There is no known antidote for Remdesivir. In the case of overdose, the subject should receive standard treatment for overdose and supportive therapy based on the subject's signs and symptoms.

Storage:

Store at 2-8°C temperature. Keep the medicine out of the reach of children.

How supplied:

Remdinil™ 100 mg Conc. Solution: Each box contains 1 vial filled with Remdesivir 100 mg concentrate for solution for IV infusion, 20 ml disposable syringe & 250 ml 0.9% NaCl solution.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH