120 mm X 245 mm

Remcor®

Remdesivir

Composition

Remcor® Concentrated Solution for IV Infusion: Each 20 ml vial contains Remdesivir INN 100 mg.

Pharmacology

Remcor® is the preparation of Remdesivir which is a prodrug that metabolizes into its active form GS-441524. An adenosine nucleotide analog, GS-441524 interferes with the action of viral RNA-dependent RNA polymerase and evades proofreading by viral exoribonuclease (ExoN), causing a decrease in viral RNA production. It was unknown whether it terminates RNA chains or causes mutations in them.

Indication

Emergency Use of **Remcor®** 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 (SpO_2) ≤ 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 adult and pediatric patients for whom use of an intravenous agent is clinically appropriate.

Dose and administration

Route of administration: Remdesivir should be administered via IV infusion only. Do not administer as an intramuscular (IM) injection.

Patient selection and treatment initiation

- Empiric treatment of hospitalized patients with suspected COVID-19 can be considered pending laboratory confirmation of SARS-CoV-2 infection.
- Remdesivir can be used at any time after onset of symptoms in hospitalized patients.
- Adult and pediatric patients weighing 40 kg and higher must have an estimated glomerular filtration rate (eGFR) determined before dosing and daily while receiving remdesivir.
- Hepatic laboratory testing should be performed in all patients prior to starting remdesivir and daily while receiving remdesivir.

Adult patients and pediatric patients weighing 40 kg and higher

- The recommended dosage of remdesivir is a single loading dose of 200 mg on Day 1 followed by once daily maintenance doses of 100 mg from Day 2.
- For patients requiring invasive mechanical ventilation and/or Extracorporeal Membrane Oxygenation (ECMO), the recommended total treatment duration is 10 days.
- For patients not requiring invasive mechanical ventilation and/or ECMO, the recommended total treatment duration is 5 days. If a patient does not demonstrate clinical improvement, treatment may be extended for up to 5 additional days for a total treatment duration of up to 10 days.
- Administer remdesivir via IV infusion over 30 to 120 minutes.

Patients with renal impairment: Patients with eGFR greater than or equal to 30 ml/min have received remdesivir for treatment of COVID-19 with no dose adjustment. The safety and efficacy of remdesivir have not been assessed in patients with severe renal impairment or ESRD. Remdesivir is not recommended in adult and pediatric patients with eGFR less than 30 ml/min unless the potential benefit outweighs the potential risk.

Patient with hepatic impairment: It is not known if dosage adjustment is needed in patients with hepatic impairment and remdesivir should only be used in patients with hepatic impairment if the potential benefit outweighs the potential risk. Hepatic laboratory testing should be performed in all patients prior to starting remdesivir and daily while receiving remdesivir.

Method of dilution

- Allow the medicine to reach the room temperature (20ºC to 25ºC) before dilution with 0.9% sodium chloride solution.
- Diluents as intravenous fluid must be used 0.9% (9 mg/ml) sodium chloride in water for injection (normal saline).
- Withdraw and discard 40 ml of 0.9% sodium chloride solution from infusion bag (250 ml) and transfer two vials (2×20 ml) of remdesivir concentrated solution into infusion bag for first dose.
- Withdraw and discard 20 ml of 0.9% sodium chloride solution from infusion bag and transfer one vial (20 ml) of remdesivir concentrated solution for the next dose to last dose.
- Gently invert the bag 20 times to mix the solution in the bag. Don't shake.
- The prepared diluted solution is stable for 4 hours at room temperature (20ºC to 25ºC) and 24 hours at refrigerated temperature (2ºC to 8ºC).
- The diluted solution is better to be used immediately.

Recommended rate of infusion

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

Contraindication

Remdesivir is contraindicated in patients with known hypersensitivity to any ingredients of remdesivir.

Warning and precaution

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 prothrombin time prolongation in some subjects but without any clinically relevant change in INR or other evidence of hepatic effect. The mechanism of these elevations is currently unknown. In nonclinical animal studies, toxicity findings were consistent with dose dependent and reversible kidney injury & dysfunction. In clinical studies, no evidence of nephro toxicity 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.

Side effects

In Ebola trial, researchers noted side effects of remdesivir that included: Increased liver enzyme levels that may indicate possible liver damage. Typical antiviral drug side effects include nausea and vomiting.

Use in pregnancy and lactation

Pregnancy: It is unknown whether remdesivir will affect a fetus or impact on pregnancy. In rats and monkeys, remdesivir affected kidney development in fetus.

Lactation: It is unknown whether or not remdesivir passes into breast milk. Consult with physician before breastfeeding.

Use in children and adolescents

Remdesivir injection, 100 mg/20 ml (5 mg/ml), should not be used for pediatric patients weighing 3.5 kg to less than 40 kg.

Drug interaction

Drug interaction with medication: Remdesivir itself is not believed to affect other medications, however, other medications may affect remdesivir. Some medications will boost the remdesivir level in the bloodstream and some will reduce it. Some antibiotics that may do this include; clarithromycin and rifampicin.

Drug interaction with food and others: Not applicable.

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 in a refrigerator at 2°C to 8°C, protected from light. Do not keep in deep fridge. Keep away from the reach of children.

Packing

Remcor® Concentrated Solution for IV Infusion: Each box contains 1 vial filled with Remdesivir INN 100 mg concentrated solution for IV infusion.

® Registered Trade Mark

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