SAFETY AND GENERAL MONITORING

Prior to starting remdesivir
• Check liver function and renal function.

During and after treatment
• Clinically monitor patients during infusion and after administration according to local practice for any side effects, (see adverse events).
• If clinically indicated, monitor liver function test and/or renal function.

ADVERSE EFFECTS AND DRUG INTERACTIONS

Adverse effects
• Common side effects include elevated transaminases, prolonged prothrombin time, nausea, rash, and headache.
• Uncommon side effects include generalized seizure, infusion related reaction, and hypersensitivity reactions.

Hypersensitivity including anaphylaxis and infusion related reactions
Although rare, hypersensitivity reactions ranging from life threatening anaphylaxis to infusion related reactions have been observed following administration of remdesivir.

1. Anaphylaxis
   • Severe potentially life-threatening allergic reaction.
   • It can cause trouble breathing, low blood pressure, swollen tongue or throat, weak and rapid pulse, nausea, vomiting, dizziness, fainting or rash.

2. Infusion-related reaction
   • Slower infusion rates, with a maximum infusion time of 120 minutes can be considered to potentially prevent these signs and symptoms.
   • May be mild to severe with diverse symptoms including hypotension, hypertension, tachycardia, bradycardia, hypoxia, fever, dyspnoea, wheezing, angioedema, rash, nausea, vomiting, diaphoresis, and shivering.

Anaphylaxis treatment
1. Stop infusion
2. Assess and secure airway
3. Administer intramuscular epinephrine
4. Administer intravenous fluids as needed
5. For bronchospasm, give bronchodilator via nebulizer or inhaler
6. Give intravenous diphenhydramine
7. (Re)assess airway and administer oxygen as needed
8. In severe anaphylaxis or if patient not improving transfer to higher level of care
* For further information, please refer to QR code/link below

Infusion-related reaction treatment
1. Stop infusion, assess for emergency signs and treat as needed.
2. For non-severe or life-threatening reactions, provide symptomatic treatment and supportive care.
3. Decision to restart infusion should be made under clinical supervision per individual patient
* For further information, please refer to QR code/link below

Drug interactions
• Co-administration of remdesivir and chloroquine or hydroxychloroquine is not recommended based on in vitro data demonstrating an antagonistic effect of chloroquine on the intracellular metabolic activation and antiviral activity of remdesivir.
• No clinical interaction studies have been performed with remdesivir, thus the overall potential for interactions is currently unknown.

Antiviral resistance
• Data is currently insufficient to ascertain how high the barrier of resistance is with SARS-CoV-2 to remdesivir. Based on experience with other similar types of antivirals, the drug will place a selective pressure for resistance mutations within individuals, with the potential to spread to the population.

REPORTING OF ADVERSE EVENTS IN PHARMACOVIGILANCE PROGRAMMES
• Report all adverse events to national or local pharmacovigilance programmes.