SAFETY ALERT

DRAP SAFTEY ALERT NO. 24

Safety Alert of Risk of Sinus Bradycardia with Remdesivir

Date: 21st of November, 2022.

Target Audience:

- Manufacturers and importers of Remdesivir;
- Healthcare Professionals; and
- Patients, consumers or caregivers.

Background:

Health Canada in August, 2021 announced that it will work with the manufacturer of Remdesivir to update the product information to include a warning on the potential risk of sinus bradycardia. Health Canada assessed case reports of sinus bradycardia in patients receiving Remdesivir in their database and in the literature and concluded that a link between the use of Remdesivir and the risk of sinus bradycardia is possible.

Previously, in June 2021, the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicine Agency (EMA) recommended a change to the product information for Remdesivir (Veklury®) to include sinus bradycardia as an adverse drug reaction. The PRAC reviewed available data on rare reported cases of bradycardia in patients treated with Remdesivir as well as data from clinical trials and the scientific literature. The PRAC concluded that a causal relationship between the use of Remdesivir and the event is reasonably possible and recommended the revision of the product information. The majority of the events of sinus bradycardia resolved a few days after the treatment with Remdesivir was discontinued.

Sinus bradycardia occurs when the heart beats slower than normal. Sinus bradycardia can very rarely cause symptoms, such as dizziness, tiredness, shortness of breath, and chest discomfort.

Action in Pakistan:

Accordingly, the case of the risk of sinus bradycardia with Remdesivir was discussed in the 1st meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) of the National Pharmacovigilance Centre (NPC), Division of Pharmacy Services, Drug Regulatory Authority of Pakistan (DRAP). The PRAEC after discussion decided as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022 (reliance mechanism) to update the prescribing information (warning & adverse drug reactions sections) of Remdesivir to include the potential risk of sinus bradycardia.

Therapeutic Goods Affected.

Name: **Remdesivir**

Remdesivir is an antiviral medicine that is indicated to treat COVID-19 in adults and adolescents with pneumonia requiring supplemental oxygen. Remdesivir is a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) nucleotide analog RNA polymerase inhibitor indicated for the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (28 days of age and older and weighing at least 3 kg) with positive results of direct SARS-CoV-2 viral testing, who are: hospitalized, or not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

Advice for patients.

Patients are advised to monitor their symptoms for sinus bradycardia and accordingly inform their healthcare professionals.

Advice for healthcare professionals.

Healthcare professionals are informed that the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) of the NPC-DRAP has decided to update the prescribing information (warning & adverse drug reactions sections) of Remdesivir to include the potential risk of sinus bradycardia. Therefore, healthcare professionals should monitor patients receiving Remdesivir for sinus bradycardia and accordingly treat the patients as appropriate.

Guidelines for reporting of Adverse Drug Reactions (ADRs):

Both healthcare professionals and patients are requested to report any suspected adverse drug reaction (ADRs) with Remdesivir to the National Pharmacovigilance Centre, Drug Regulatory Authority of Pakistan through Med Vigilance E-Reporting system available on the DRAP website. Similarly, ADRs can also be reported through MedSafety App which is available for download from App store (for iOS devices) and Google Play (for Android devices).

References:

1. Minutes of 1st meeting of Pharmacovigilance Risk Assessment Expert Committee.
2. Minutes of Meeting of PRAC of European Medicines Agency.

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