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[Clin Pharmacol Ther.](#) 2021 Apr;109(4):1021-1024. doi: 10.1002/cpt.2145. Epub 2021 Jan 16.

# Remdesivir and Acute Renal Failure: A Potential Safety Signal From Disproportionality Analysis of the WHO Safety Database

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PMID: 33340409 DOI: [10.1002/cpt.2145](https://doi.org/10.1002/cpt.2145)

## Abstract

Remdesivir is approved for emergency use by the US Food and Drug Administration (FDA) and authorized conditionally by the European Medicines Agency (EMA) for patients with coronavirus disease 2019 (COVID-19). Its benefit-risk ratio is still being explored because data in the field are rather scant. A decrease of the creatinine clearance associated with remdesivir has been inconstantly reported in clinical trials with unclear relevance. Despite these uncertainties, we searched for a potential signal of acute renal failure (ARF) in pharmacovigilance postmarketing data. An analysis of the international pharmacovigilance postmarketing databases (VigiBase) of the World Health Organization (WHO) was performed, using two disproportionality methods. Reporting odds ratio (ROR) compared the number of ARF cases reported with remdesivir, with those reported with other drugs prescribed in comparable situations of COVID-19 (hydroxychloroquine, tocilizumab, and lopinavir/ritonavir). The combination of the terms "acute renal failure" and "remdesivir" yielded a statistically significant disproportionality signal with 138 observed cases instead of the 9 expected. ROR of ARF with remdesivir was 20-fold (20.3; confidence interval 0.95 [15.7-26.3],  $P < 0.0001$ ) that of comparative drugs. Based on ARF cases reported in VigiBase, and despite the caveats inherent to COVID-19 circumstances, we detected a statistically significant pharmacovigilance signal of nephrotoxicity associated with remdesivir, deserving a thorough qualitative assessment of all available data. Meanwhile, as recommended in its Summary of Product Characteristics, assessment of patients with COVID-19 renal function should prevail before and during treatment with remdesivir in COVID-19.

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