

Post-Marketing Safety Concerns with Nirmatrelvir: A Disproportionality Analysis of Spontaneous Reports Submitted to the FDA Adverse Event Reporting System

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Abstract

Aim: Nirmatrelvir as a new 3CL protease inhibitor for treating COVID-19 drug of antiviral drug, the potential side effects have not yet been fully studied yet. The aim of this study was to identify potential risk of Nirmatrelvir by analyzing post-marketing safety data based on the largest publicly available worldwide pharmacovigilance database. **Methods:** We analyzed Nirmatrelvir adverse events to detect and characterize relevant safety signals based on the FDA Adverse Event Reporting System database in 2022. Case/non-case approach were used to estimate the reporting odds ratio (ROR) and information component (IC) with relevant confidence intervals (95% CI) for AEs with ≥ 4 counts. **Results:** Total of 26846 cases were included. Disease recurrence [ROR(95%CI)=413.2(395.6-431.59)], dysgeusia [ROR(95%CI)=110.84(106.04-115.85)], anosmia [ROR(95%CI)=15.21(12.76-18.11)], ageusia [ROR(95%CI)=9.80(8.50-11.3)] and urticaria [ROR(95%CI)=1.91(1.69-2.17)] were the main safety signals. In addition, abdominal pain upper and skin toxicity were two specific safety signals of Nirmatrelvir. In pregnant population, a significant increased ROR was found in life-threatening [ROR(95%CI)=5.12(1.38-19.00)]. **Conclusion:** We identified that disease recurrence, dysgeusia, abdominal pain upper and skin toxicity were the main and specific safety signals of Nirmatrelvir. Clinician and pharmacist should pay attention on these AEs. Notably, a potential risk of Nirmatrelvir in pregnant population should be alerted.

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