



SFDA SAFETY SIGNAL

“A signal is defined by the SFDA as reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. A signal is a hypothesis together with data and arguments and it is important to note that a signal is not only uncertain but also preliminary in nature”

29-09-2025

Saudi Food and Drug Authority (SFDA) – Safety Signal of Dasabuvir and the Risk of Increased appetite

*The Saudi Food and Drug Authority (SFDA) recommends all health care professionals to be aware of the safety signal of **Increased appetite** associated with the use of **Dasabuvir**. The signal has been originated as a result of routine pharmacovigilance monitoring activities.*

Introduction

Dasabuvir is a nonnucleoside inhibitor of the hepatitis C virus (HCV) RNA-dependent RNA polymerase encoded by the gene for nonstructural protein 5B (NS5b), which is essential for replication of the viral genome; its antiviral activity is limited to HCV genotype 1. ^[1] Increased appetite means having an excess desire for food. An increased appetite can be a symptom of different diseases. For example, it may be due to a mental condition or a problem with an endocrine gland. Causes may include: Anxiety, Certain medicines, Bulimia (most common in women 18 to 30 years old) and Diabetes mellitus. ^[2] The aim of this review is to evaluate the risk of Increased appetite associated with the use of Dasabuvir and to suggest regulatory recommendations if required.

Methodology

Signal Detection team at SFDA performed a signal review using National Pharmacovigilance Center (NPC) database, and World Health Organization (WHO) database, Vigibase, with literature screening to retrieve all related information to assess the causality between Increased appetite and Dasabuvir use. The search conducted on August 2025.

Results

Cases Review: Signal detection team at SFDA have searched Saudi national database and WHO database to find individual case safety reports (ICSRs). The WHO database resulted in 76 global case-reports while only one local case found. The authors used signal detection tool (Vigilyze) to retrieve global cases. ^[3] Authors also applied WHO-UMC causality assessment criteria on the extracted ICSRs with completeness score 0.8 and above (16 cases). ^[4] Among them, 15 cases were possibly linked to Dasabuvir, while one case could not be assessed because of a lack of important information.

Datamining: The disproportionality of the observed and the expected reporting rate for drug/adverse drug reaction pair is estimated using information component (IC), a tool developed by WHO-UMC to measure the reporting ratio. Positive IC reflects higher statistical association while negative values indicate less statistical association. The IC result is (4.1) for this drug/ADR combination which reflects strong positive statistical association. ^[4]



Conclusion

The weighted cumulative evidence identified from assessed cases and disproportionality analysis are suggestive for causal association between Dasabuvir and Increased appetite. Health care professionals and health regulators must be aware of the potential risk in drug recipients.

Report Adverse Drug Events (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to continue reporting adverse drug reactions (ADRs) resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance Center (NPC)
Saudi Food and Drug Authority-Drug sector
4904 northern ring branch rd
Hittin District
Riyadh 13513 – 7148
Kingdom of Saudi Arabia
Toll free number: 19999
Email: NPC.Drug@sfda.gov.sa

References:

- 1- David W. Kimberlin (2018). Principles and Practice of Pediatric Infectious Diseases (Fifth Edition). Antiviral Agents chapter.
- 2- MedlinePlus.gov. (2025). Appetite – increased: Available from: <https://medlineplus.gov/ency/article/003134.htm>
- 3- Vigilyze.who-umc.org. 2025. [online] Available at: <https://vigilyze.who-umc.org/>
- 4- World Health Organization WHO (2013). WHO-UMC system for standardised case causality assessment. Available at <https://www.who.int/publications/m/item/WHO-causality-assessment>