



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”

18-05-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Paliperidone and the Risk of Dissociation

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

Introduction

Paliperidone is used to treat the symptoms of schizophrenia and schizoaffective disorder (a mental illness with symptoms of schizophrenia and a mood disorder such as depression or mania). Paliperidone is in a class of medications called atypical antipsychotics. It works by changing the activity of certain natural substances in the brain. ^[1] Dissociative disorders are mental health conditions that involve experiencing a loss of connection between thoughts, memories, feelings, surroundings, behavior and identity. These conditions include escape from reality in ways that are not wanted and not healthy. This causes problems in managing everyday life. Dissociative disorders usually arise as a reaction to shocking, distressing or painful events and help push away difficult memories. ^[2] The aim of this review is to evaluate the risk of Dissociation associated with the use of Paliperidone 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 potential link between Dissociation and Paliperidone use.

Results

Case 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 29 global case reports while 1 local case found which triggers this investigation. The authors used signal detection tool (Vigilyze) to retrieve global cases. ^[3] The author applied Who Causality assessment tool on the extracted cases with completeness 0.6 and above (8 cases). ^[3] Among them, 2 cases were probably linked to Paliperidone, 3 cases resulted in possible association, and 1 case resulted in unlikely association, while the remaining two cases lacked sufficient information for a proper assessment.

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 indicates less statistical association. The IC result is (1.4) for this drug/ADR combination which reflects positive statistical association. ^[3]



Conclusion

The weighted cumulative evidence identified from assessed local and global cases alongside with disproportionality analysis are suggestive for causal association between Paliperidone and Dissociation. 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@sfd.gov.sa

References

- 1- U.S. National Library of Medicine. (2025, November 15). Paliperidone. MedlinePlus. <https://medlineplus.gov/druginfo/meds/a607005.html>
- 2- Mayo Clinic. (2023, August 31). Dissociative disorders: Symptoms and causes. Mayo Clinic. <https://www.mayoclinic.org/diseases-conditions/dissociative-disorders/symptoms-causes/syc-20355215>
- 3- Vigilyze.who-umc.org. 2026. [online] Available at: <https://vigilyze.who-umc.org/>