



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”

26-02-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of CARBIDOPA; LEVODOPA and the Risk of Seizures

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

Introduction

Carbidopa;Levodopa is an Antiparkinsonian agent. It used for treatment of Parkinson’s disease and syndrome. Carbidopa is a peripheral dopa decarboxylase inhibitor. It prevents metabolism of levodopa to dopamine in the peripheral circulation, ensuring that a higher proportion of the dose reaches the brain, where dopamine acts. ^[1] A seizure is a sudden burst of electrical activity in the brain. It can cause changes in behavior, movements, feelings and levels of consciousness. Epilepsy is defined as having two or more seizures at least 24 hours apart that don't have a known cause. But epilepsy doesn't cause all seizures. ^[2] The aim of this review is to evaluate the risk of Seizures associated with the use of CARBIDOPA; LEVODOPA 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 Seizures and CARBIDOPA; LEVODOPA use. The search conducted on January 2026.

Results

Case Review: Signal detection team at SFDA have searched Saudi national database and WHO database to find individual case safety reports (ICSRs). A total of 408 global case reports were retrieved from the WHO database, while 2 local case reports were identified from the NPC database, which collectively initiated the present signal 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 score (> 0.8). ^[3] Among them, seven cases were probably linked to CARBIDOPA; LEVODOPA, twelve cases resulted in possible association, nine cases resulted in unlikely association, while the remaining twelve 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 (-0.2) for this drug/ADR combination which reflects negative statistical association. ^[3]



Literature: The signal team conducted a literature search to identify publications linking this adverse drug reaction to CARBIDOPA; LEVODOPA. The search identified three published studies suggesting a possible association between the drug and this potential risk. [4], [5], [6]

Conclusion

The weighted cumulative evidence identified from assessed local and global cases, in addition to literature are suggestive for causal association between CARBIDOPA; LEVODOPA and Seizures. 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- Sinemet 25mg/250mg (2024) Medicines.ie. Available at: <https://www.medicines.ie/medicines/sinemet-25mg-250mg-35436/spc>.
- 2- MayoCliniceDiseases- Seizures: <https://www.mayoclinic.org/diseases-conditions/seizure/symptoms-causes/syc-20365711>
- 3- Vigilyze.who-umc.org. 2026. [online] Available at: <https://vigilyze.who-umc.org/>.
- 4- Product information (2020) Canada.ca. Available at: <https://health-products.canada.ca/dpd-bdpp/info?lang=eng&code=69226>.
- 5- Center (2025) April - June 2025 | Potential Signals of Serious Risks/New Safety Info, U.S. Food and Drug Administration. Available at: <https://www.fda.gov/drugs/fdas-adverse-event-reporting-system-faers/april-june-2025-potential-signals-serious-risksnew-safety-information-identified-fda-adverse-event>.
- 6- Bamford, C.R. et al. (1990) 'Serial Epilepsy Caused by Levodopa/Carbidopa Administration in two Patients on Hemodialysis', International Journal of Neuroscience, 50(3-4), pp. 209–214. Available at: <https://doi.org/10.3109/00207459008987173>.