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 m ore 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"

19-04-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Carboplatin and the Risk of Hypothyroidism

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

Introduction

Carboplatin, produces predominantly interstrand DNA cross-links rather than DNA-protein cross-links. This effect is apparently cell-cycle nonspecific. Carboplatin injection is indicated for the initial treatment of advanced ovarian carcinoma in established combination with other approved chemotherapeutic agents. [1] Hypothyroidism results from low levels of thyroid hormone with varied etiology and manifestations. Hypothyroidism is primarily categorized as primary and secondary hypothyroidism. In primary hypothyroidism, the thyroid gland cannot produce adequate amounts of thyroid hormone. [2] The aim of this review is to evaluate the risk of Hypothyroidism associated with the use of Carboplatin 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 Hypothyroidism and Carboplatin use. The search conducted on March 2026.

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 451 global cases reports while the NPC database resulted in 1 local case report which triggers this investigation. The authors used signal detection tool (Vigilyze) to retrieve global cases. [3] The author applied WHO Causality assessment tool on 30 cases with top completeness score. (>0.93). [3] Among them, seventeen cases were possibly linked to Carboplatin, eight cases resulted in unlikely association, while the remaining five 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 (1.6) 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 Carboplatin and Hypothyroidism. 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. Nih.gov. (2016). DailyMed - CARBOPLATIN- carboplatin injection solution. [online] Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f4baa639-287b-4d97-923f-ce5c6add531c
2. Patil N, Rehman A, Anastasopoulou C, et al. Hypothyroidism. [Updated 2024 Feb 18]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK519536/
3. Vigilyze.who-umc.org. 2026. [online] Available at: https://vigilyze.who-umc.org/.