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"

26-06-2025

Saudi Food and Drug Authority (SFDA) – Safety Signal of Vitamin B complex and the Risk of Dysgeusia

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

Introduction

Vitamin B complex is indicated where a deficiency of the relevant vitamins exists. It is indicated for the treatment of clinical and sub-clinical vitamin B deficiency states (manifestations of which include glossitis, stomatitis, cheilosis, the heart manifestations of beriberi, the skin manifestations of pellagra, corneal vascularisation and polyneuritis). [1] Dysgeusia (bad taste) is a disorder that distorts the sense of taste. People with this condition feel that all foods taste metallic, sweet, sour or bitter. Many things can cause dysgeusia, like smoking, medical conditions, medication or poor oral hygiene. [2] The aim of this review is to evaluate the risk of Dysgeusia associated with the use of Vitamin B complex 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 Dysgeusia and Vitamin B complex use. The search conducted on April 2025.

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 identified only five global case reports, whereas the national database in Saudi Arabia contained 3,371 local ICSRs. The authors used signal detection tool (Vigilyze) to retrieve local and global cases. [3] Authors applied WHO-UMC causality assessment criteria on 50 local cases, which resulted in possible causal. In addition, the five global cases were extracted from the WHO database and among them; one case was possibly linked to Vitamin B complex, while the remaining four were considered unassessable due to insufficient information. [4]

Literature: The signal team conducted a literature search to identify publications linking this adverse drug reaction to Vitamin B complex. The search revealed a published article reporting dysgeusia following the use of Vitamin B complex. [5]

Conclusion

The weighted cumulative evidence identified from assessed cases and literature are suggestive for causal association between Vitamin B complex and Dysgeusia. 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. (2021). DailyMed - VITAMIN B COMPLEX- thiamine hydrochloride, riboflavin 5 phosphate sodium, dexpanthenol and niacinamide injection. [online] Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=282ccec8-9bcd-4571-9b91-bbb96ef2620d

2- Cleveland Clinic (2021). Dysgeusia: Definition, Treatment & Causes. [online] Cleveland Clinic. Available at: https://my.clevelandclinic.org/health/diseases/22047-dysgeusia

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

5- Delompré, T., Belloir, C., Martin, C., Salles, C., & Briand, L. (2022). Detection of bitterness in vitamins is mediated by the activation of bitter taste receptors. Nutrients, 14(19), 4141.