



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”

26-04-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Metformin Hydrochloride and the Risk of Dysphagia

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

Introduction

Metformin, an antidiabetic agent, was approved by the U.S. Food and Drug Administration (FDA) in 1994 for treating type 2 diabetes. This medication comes in both immediate- and extended-release formulations and is often combined with other antidiabetic agents. The off-label indications of metformin include managing gestational diabetes, addressing weight gain issues caused by antipsychotic medication, preventing type 2 diabetes, and treating and preventing polycystic ovary syndrome (PCOS).^[1] Dysphagia or difficulty swallowing is a symptom of many different medical conditions. These conditions include nervous system and brain disorders, muscle disorders and physical blockages in your throat. Treatment for swallowing issues may include medications, changes to your eating habits and, sometimes, procedures.^[2] The aim of this review is to evaluate the risk of Dysphagia associated with the use of Metformin Hydrochloride 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 Dysphagia and Metformin Hydrochloride 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 319 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 (24 cases).^[3] Among them, 6 cases were probably linked to Metformin Hydrochloride, 7 cases resulted in possible association, and 4 cases resulted in unlikely association, while the remaining seven cases lacked sufficient information for a proper assessment.



Literature: The signal team conducted a literature search to identify publications linking this adverse drug reaction to Metformin Hydrochloride. The search identified multiple 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 alongside with literature are suggestive for causal association between Metformin Hydrochloride and Dysphagia. 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- Corcoran, C., & Jacobs, T. F. (2018). Metformin.
- 2- Cleveland Clinic. (2023, August 20). Dysphagia (difficulty swallowing). Cleveland Clinic. <https://my.clevelandclinic.org/health/symptoms/21195-dysphagia-difficulty-swallowing>
- 3- Vigilyze.who-umc.org. 2026. [online] Available at: <https://vigilyze.who-umc.org/>
- 4- Krentz, A. J., & Bailey, C. J. (2019). Practical insights into improving adherence to metformin therapy in type 2 diabetes. *Clinical Diabetes*, 37(2), 160–167. <https://doi.org/10.2337/cd18-0049>
- 5- Zdilla, M. J. (2015). Metformin with either histamine H2-receptor antagonists or proton pump inhibitors: A polypharmacy recipe for neuropathy via vitamin B12 depletion. *Clinical Diabetes*, 33(2), 90–95. <https://doi.org/10.2337/diaclin.33.2.90>
- 6- Nabrdalik, K., et al. (2022). Gastrointestinal adverse events of metformin treatment in patients with type 2 diabetes mellitus: A systematic review and meta-analysis. *Frontiers in Endocrinology*, 13, 975912. <https://doi.org/10.3389/fendo.2022.975912>