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"

30-4-2023

Saudi Food and Drug Authority (SFDA) – Safety Signal of Prednisolone and the Risk of Hypomagnesaemia

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

Introduction

Prednisolone is a medicine used to treat a wide range of health problems including allergies, blood disorders, skin diseases, inflammation, infections and certain cancers and to prevent organ rejection after a transplant. It helps by reducing swelling (inflammation) and can also calm down your immune system. [1] Magnesium is an important electrolyte. It is a key part of many reactions that occur in the human body, affecting cellular function, nerve conduction, and other needs. Normal serum magnesium levels are between 1.46 and 2.68 mg/dL. Hypomagnesemia is an electrolyte disturbance caused by a low serum magnesium level (less than 1.46 mg/dL) in the blood. Hypomagnesemia can be attributed to chronic disease, alcohol use disorder, gastrointestinal losses, renal losses, and other conditions. Signs and symptoms of hypomagnesemia include mild tremors and generalized weakness to cardiac ischemia and death. [2] The aim of this review is to evaluate the risk of Hypomagnesaemia associated with the use of Prednisolone 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 Hypomagnesaemia and Prednisolone use. The search conducted on March 2023.

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 28 global case-reports. [3] The authors applied WHO-UMC causality assessment criteria on the 28 ICSRs, which resulted in almost half of them are possibly linked to Prednisolone (13 possible + 13 not assessable +2 unlikely = 28 ICSRs). [4]

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, considering the null value equal to zero. The results of (IC= 0.6) revealed a positive statistical association for the drug/ADR combination. [3]

Conclusion

The weighted cumulative evidence identified from assessed cases and data mining are sufficient to suggest causal association between Prednisolone and Hypomagnesaemia. 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- Mother To Baby | Fact Sheets [Internet]. Brentwood (TN): Organization of Teratology Information Specialists (OTIS); 1994-. Prednisone/Prednisolone. 2022 Jul. Available from: https://www.ncbi.nlm.nih.gov/books/NBK582908/
2- Gragossian A, Bashir K, Bhutta BS, et al. Hypomagnesemia. [Updated 2022 Nov 4]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK500003/
3- Vigilyze.who-umc.org. 2023. [online] Available at: https://vigilyze.who-umc.org/ [Accessed 26/03/2023].
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 [Accessed 26/03/2023].