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"

12-08-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Azathioprine and the Risk of Optic neuritis

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

Introduction

Azathioprine is a medication used in the management and treatment of active rheumatoid arthritis and the prevention of kidney transplant rejection. [1] Optic neuritis, or inflammation of the optic nerves, is a frequent cause of acute optic nerve injury in children and adults. Multiple causes of optic nerve inflammation exist: autoimmunity, infection, granulomatous disease, paraneoplastic disorders, and demyelination. [2] The aim of this review is to evaluate the risk Optic neuritis associated with the use of Azathioprine 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 Optic neuritis and Azathioprine use.

Results

Cases 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 36 global case 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 cases with compeleteness score 0.4 and above = 13 ICSRs. Two cases were considered probably associated with azathioprine, two showed a possible association, two were assessed as unlikely to be associated, and the remaining seven cases were unassessable.

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 indicate less statistical association. The IC result is (1.3) 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 Azathioprine and Optic neuritis. 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- Mohammadi, O., & Kassim, T. A. (2019). Azathioprine.
2- Bennett, J. L. (2019). Optic neuritis. Continuum: lifelong learning in neurology, 25(5), 1236-1264.
3- Vigilyze.who-umc.org. 2026. [online] Available at: https://vigilyze.who-umc.org/