



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 Acetylsalicylic Acid and the Risk of Visual disturbance

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

Introduction

Acetylsalicylic Acid is a type of nonsteroidal anti-inflammatory drug (NSAID) that can treat mild to moderate pain, inflammation or arthritis. It also lowers your risk of heart attack, stroke or blood clot. Children and teenagers shouldn't use this medication to treat their symptoms unless directed by their healthcare provider ^[1] Visual disturbance is when you experience a short spell of flashing or shimmering of light in your sight. The symptoms normally last around twenty minutes before your sight returns to normal. Usually, there is no headache during the visual disturbance. A visual disturbance should not be confused with a retinal or ocular migraine where there is a partial or total loss of vision in one eye, normally with a headache. Visual disturbance is a common condition among people who are affected by migraines, although they can affect anyone. Common triggers include: stress, tiredness, flashing or flickering lights (including driving through a row of trees in bright sunlight), glare (bright sheen of light reflected from a window, computer monitor, or white paper), exercise, bending over, dehydration, certain foods such as chocolate, cheese or alcohol, excessive heat. ^[2] The aim of this review is to evaluate the risk of Visual disturbance associated with the use of Acetylsalicylic Acid 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 Visual disturbance and Acetylsalicylic Acid 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 414 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 top 25 cases with completeness score of (0.9) and above. Among them, 14 cases resulted in possible association, and 10 cases resulted in unlikely association, while the remaining case lacked sufficient information for a proper assessment.



Literature: The signal team conducted a literature search to identify publications linking this adverse drug reaction to Acetylsalicylic Acid. The search identified two published studies suggesting a possible association between the drug and this potential risk. ^{[4][5]}

Conclusion

The weighted cumulative evidence identified from assessed local and global cases alongside with literature are suggestive for causal association between Acetylsalicylic Acid and Visual disturbance. 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@sfd.gov.sa

References

- 1- Cleveland Clinic. (n.d.). Aspirin tablets: Uses, side effects, and warnings. Cleveland Clinic. <https://my.clevelandclinic.org/health/drugs/20592-aspirin-tablets>
- 2- Look After Your Eyes. (n.d.). Visual disturbance (visual aura) – Migraine with aura. Look After Your Eyes. <https://lookafteryoureyes.org/eye-conditions/visual-disturbance-visual-aura-migraine-with-aura/>
- 3- Vigilyze.who-umc.org. 2026. [online] Available at: <https://vigilyze.who-umc.org/>
- 4- Liew, G., Mitchell, P., Wong, T. Y., Rochtchina, E., & Wang, J. J. (2013). The association of aspirin use with age-related macular degeneration. *JAMA internal medicine*, 173(4), 258-264.
- 5- Michalska-Małecka, K., Regucka, A., Śpiewak, D., Sosnowska-Pońska, M., & Niewiem, A. (2016). Does the use of acetylsalicylic acid have an influence on our vision?. *Clinical Interventions in Aging*, 1567-1574.