

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”

28-10-2024

Saudi Food and Drug Authority (SFDA) – Safety Signal of Liraglutide and the Risk of Alopecia

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

Introduction

Liraglutide is a glucagon like peptide 1 (GLP-1) receptor agonist indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management. ^[1] Alopecia means hair loss, which can be from a single area or several areas of the head and body. There are many types of alopecia, such as male or female pattern hair loss and alopecia areata. Alopecia can be caused by many different things including stress, health conditions, medicines or damage to the hair. ^[2] The aim of this review is to evaluate the risk of Alopecia associated with the use of Liraglutide 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 Alopecia and Liraglutide use. The search conducted on July 2024.

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 404 global case-reports while no local cases found. The authors used signal detection tool (Vigilyze) to retrieve all reported global cases. ^[3] Authors also applied WHO-UMC causality assessment criteria on 30 extracted ICSR with top completeness score of 0.9 and 1.0. ^[4] Among them, 18 cases were probably and possibly linked to Liraglutide, and 11 cases assessed as not assessable due to lack of valuable information, while the remaining one case assessed as unlikely.

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. The IC result is (0.1) for this drug/ADR combination which reflects slightly positive statistical association. ^[4]

Additional evidence: This signal been detected and evaluated by international regulatory authorities. ^[5,6]

Conclusion

The weighted cumulative evidence identified from assessed cases is suggestive for causal association between Liraglutide and Alopecia. 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- DailyMed - saxenda- liraglutide injection, solution (no date) U.S. National Library of Medicine. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3946d389-0926-4f77-a708-0acb8153b143> [Accessed: 10/07/2024].
- 2- Alopecia (hair loss), healthdirect. Available at: <https://www.healthdirect.gov.au/alopecia> [Accessed: 13/07/2024]
- 3- Vigilyze.who-umc.org. 2024. [online] Available at: <https://vigilyze.who-umc.org/> [Accessed: 14/07/2024].
- 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: 14/07/2024].
- 5- Center for Drug Evaluation and Research (no date) July - September 2023: Potential signals of serious risks/new safety, U.S. Food and Drug Administration. Available at: <https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/july-september-2023-potential-signals-serious-risksnew-safety-information-identified-fda-adverse> [Accessed: 11/07/2024].
- 6- EMA statement on ongoing review of GLP-1 receptor agonists (2023) EMA statement on ongoing review of GLP-1 receptor agonists | European Medicines Agency. Available at: <https://www.ema.europa.eu/en/news/ema-statement-ongoing-review-glp-1-receptor-agonists> [Accessed: 14/07/2024].